

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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NMT Medical, Inc.,

Plaintiff,

v.

Civil Action # 04-12565 NG

AGA Medical Corporation

Defendant.

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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT’S MOTION TO DISMISS  
OR, IN THE ALTERNATIVE, TO TRANSFER VENUE TO THE U. S. DISTRICT  
COURT FOR THE DISTRICT OF MINNESOTA**

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Defendant AGA Medical Corp. (“AGA”) asks the Court to dismiss this action in favor of the earlier-filed declaratory judgment action currently pending in the U.S. District Court for the District of Minnesota (“the Minnesota District Court”). Alternatively, AGA requests a change of venue to the U.S. District Court for the District of Minnesota.

AGA filed a declaratory judgment action in the Minnesota District Court eight weeks before the present action was filed. Judicial economy and fairness would be better served if this case was dismissed and the parties proceeded in the declaratory judgment action, or, in the alternative, if the case was venued in Minnesota and consolidated with the earlier-filed declaratory judgment action.

Moreover, the Minnesota District Court is the more convenient and appropriate venue since the present action could have been brought in Minnesota, key defense witnesses are reside in Minnesota, and Plaintiff NMT Medical, Inc. (“NMT”) has already consented to jurisdiction there.

### **STATEMENT OF FACTS**

This patent dispute is about devices used to treat heart defects. The devices are implanted using a catheter and are used to block holes which left untreated can cause shortness of breath, pulmonary vascular obstruction disease, congestive heart failure, stroke or even death in the patient.

AGA is a corporation organized and existing under the laws of the State of Minnesota, and runs its operations out of Golden Valley, Minnesota. (Declaration of Jodi Raus ¶ 2) AGA specializes in the development and manufacture of innovative medical devices. (Id.) AGA has developed and patented the AMPLATZER® Septal Occluder, which was the first device approved in the United States for closure of congenital heart defects such as secundum atrial septal defects (“ASD”), which are holes in the wall between the right and left atria of the heart. (Id.) AGA has also developed patented, and/or secured FDA approval for various other devices for treating other conditions. (Id.)

For its efforts, AGA has been awarded U.S. Patent Nos. 5,725,552; 5,846,261; 5,944,738; and 6,123,715. (Declaration of Jodi Raus, ¶ 3.) The primary inventors of each of these inventions are Messrs. Kurt and Curtis Amplatz. (Id.) The documents related to the conception and reduction-to-practice of the AGA’s AMPLATZER® Septal Occluder, which is the product accused of infringement in this action, are all kept in AGA’s Minnesota offices. (Declaration of Jodi Raus ¶ 4) Messrs. Kurt and Curtis Amplatz are no longer employees of AGA, but are residents of the State of Minnesota. (Declaration of Jodi Raus ¶ 5) In addition, the relevant witnesses regarding the manufacture, use, and sale of the AMPLATZER® Septal Occluder all reside in Minnesota. (Declaration of Jodi Raus ¶ 6)

NMT is a Delaware corporation having its principal place of business in Boston, Massachusetts. (Declaration of Jodi Raus, ¶ 7.) NMT manufactures and sells a device for sealing ASD under the trademarks CardioSEAL and STARFlex. (Declaration of Jodi Raus, ¶ 8.) NMT has numerous contacts with Minnesota. First, according to NMT's website, two of its products, the CardioSEAL and STARFlex devices have been the subject of clinical testing at Abbot Northwestern Hospital in Minneapolis, Minnesota and United Hospitals in Saint Paul, Minnesota. (Declaration of Jodi Raus, ¶ 9.) Second, also according to its website, NMT has trained a number of Minnesota physicians to implant the CardioSEAL device. (Declaration of Jodi Raus, ¶ 10.) Third, NMT sells its products into Minnesota for implantation by these physicians. Fourth, NMT has consented to jurisdiction and venue in Minnesota by initiating NMT Medical, Inc. et al v. Cardia, Inc., No. 04-cv-4200-JNE-JGL (D. Minn. filed Sept. 22, 2004), another patent infringement action relating to another cardiac occlusion device that was filed against another company located in Minnesota. (Declaration of Jodi Raus, ¶ 11.)

Dr. Lloyd Marks is a pediatric cardiologist living in the State of New Jersey. (Declaration of Jodi Raus, ¶ 12.) Dr. Marks claims to own the patent at issue in this action, U.S. Patent 5,108,420 ("the '420 patent"). (Declaration of Jodi Raus, ¶ 13.) NMT claims to have purchased an exclusive license under the '420 patent from Dr. Marks. (Declaration of Jodi Raus, ¶ 14.) It is that license that NMT asserts as the basis for its standing to bring this action against AGA.

According to NMT's filings with the Security and Exchange Commission, the licensing agreement between NMT and Dr. Marks grants NMT the exclusive right to make, use and sell inventions covered by the '420 patent, and the exclusive right to sublicense others to make use and sell such inventions. (Id.) In exchange, Dr. Marks is to receive substantial payments from

NMT including royalty payments based upon the net sales price of all licensed products.

(Declaration of Jodi Raus, ¶ 15.) Dr. Marks is also to receive warrants to purchase common stock in NMT. (Id.) Under the licensing agreement, Dr. Marks agreed to participate in the clinical trials and animal experimentation of the inventions covered by the '420 patent ("licensed products"). (Declaration of Jodi Raus, ¶ 16.) Dr. Marks also was required to provide necessary and useful technical information to assist in the manufacture, use, sale, and installation of the licensed products. (Declaration of Jodi Raus, ¶ 17.) Most importantly, Dr. Marks agreed to cooperate with NMT in any legal action taken against accused infringers. (Declaration of Jodi Raus, ¶ 18.)

On December 10, 1998, NMT commenced litigation in the U.S. District Court for the District of Massachusetts against AGA for infringement of the '420 patent (hereinafter referred to as "the 1998 Action"). (Declaration of Jodi Raus, ¶ 19.) The 1998 Action was captioned Nitinol Medical Technologies, Inc. and Lloyd A. Marks v. AGA Medical Corp., 98-cv-12506-NG (D. Mass. filed Dec. 10, 1998). (Id.) During the course of the 1998 Action, AGA moved for summary judgment both on non-infringement and invalidity grounds. (Id.) In its summary judgment motion, AGA relied on prior art not considered by the United States Patent and Trademark Office ("Patent Office") during the prosecution of the '420 patent. (Declaration of Jodi Raus, ¶ 20.) In response to AGA's summary judgment motion, NMT asked the Court to stay litigation so the Patent Office could "reexamine" the '420 patent in view of the prior art. (Id.) AGA objected to the stay and asked the Court to enter summary judgment. (Id.) On April 25, 2001, the Court stayed the 1998 Action pending the outcome of the reexamination of the '420 patent, without hearing argument or ruling on the then-pending summary judgment motion. (Id.) On June 21, 2001, Dr. Marks filed a request for reexamination. On December 1, 2003,

more than 2 ½ years after the stay order, this Court dismissed the 1998 Action without prejudice because the reexamination was not complete. (Declaration of Jodi Raus, ¶ 21.)

While the cases currently pending in Minnesota and Massachusetts are the same, they are very different than the earlier case between the parties that was stayed and then dismissed by this Court. On a more general level, the claims which define the scope of the patent have changed. The original '420 patent contained eleven claims. During the course of the *ex parte* reexamination, efforts were made to add 69 additional claims. Currently, there are 67 claims pending before the Patent Office as part of the reexamination. Changes also have been made to the drawings and specification of the patent during the reexamination.

On a more substantive level, during reexamination the Patent Office Examiner repeatedly rejected the claims of the '420 patent based on German Patent document DD 233,303 A1 (Munster). (Declaration of Jodi Raus, ¶ 22.) While on August 19, 2004, the Patent and Trademark Office Board of Appeals reversed the examiner's rejection on very narrow grounds, it is beyond dispute that statements were made by and on Dr. Marks' behalf, by the patent examiner and by the Board of Appeals that related to the proper interpretation of both the original 11 patent claims and those sought to be added as part of the reexamination. (*Id.*) The reexamination is still not complete. As such, when it comes out of reexamination, the '420 patent not only will be a different patent with a different Patent Office prosecution history. It will also have a different patent number.

AGA brought the Minnesota action in response to new threats made by NMT. On September 7, 2004, NMT issued a press release in which John E. Ahern, the President and CEO of NMT, declared:

“[t]he Board of Appeals decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical

has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively.”

(emphasis added). (Declaration of Jodi Raus, ¶ 23.) NMT then directly informed John Borg, the interim CEO of AGA, of the Patent Office Board of Appeals’ decision. (Declaration of Jodi Raus, ¶ 24.)

Fearing that NMT would once again assert its patent, AGA brought a Complaint for Declaratory Judgment against NMT and Dr. Marks seeking a judgment that the ’420 patent is invalid and not infringed by AGA. (Declaration of Jodi Raus, ¶ 25.) AGA filed its Complaint on October 13, 2004 in the U.S. District Court for the District of Minnesota. (*Id.*) The case is captioned AGA Medical Corp. v. Nitinol Medical Technologies, Inc. et al., 04-cv-4486-JMR-FLN (D. Minn. Oct. 13, 2004). (*Id.*) On October 14, 2004, as a professional courtesy, AGA notified NMT’s counsel that they had filed the declaratory judgment action in Minnesota. (Declaration of Jodi Raus, ¶ 26.) NMT and Dr. Marks were duly served with the Summons, Complaint and exhibits on January 20, 2005. (Declaration of Jodi Raus, ¶ 27.)

On December 7, 2004, nearly eight weeks after AGA initiated the declaratory judgment action in Minnesota, NMT brought the present action in this Court. (Declaration of Jodi Raus, ¶ 28.) NMT’s Complaint in this action is for the identical subject matter as the declaratory judgment action. (Declaration of Jodi Raus, ¶ 28.)

### **LEGAL ARGUMENT**

#### **I. THE COURT SHOULD DECLINE JURISDICTION OVER NMT’S COMPLAINT PURSUANT TO THE FIRST-TO-FILE RULE.**

When two identical actions are proceeding concurrently in two federal courts, the first filed action is generally preferred in order to avoid duplicative and wasteful litigation. Cianbro Corp. v. Curran-Lavoie, Inc., 814 F.2d 7, 11 (1st Cir. 1987). The first-to-file rule is a doctrine

of federal comity which permits a district court to decline jurisdiction over an action when a complaint involving the same parties and issue has already been filed in another district. See, e.g., Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co., 342 U.S. 180, 183 (1952). The decision to apply the first-to-file rule is discretionary. Id. The first-to-file rule gives the court in which the second suit is filed three options: transfer, stay or dismiss the second suit. See Alltrade, Inc. v. Uniweld Products, Inc., 946 F.2d 622, 623 (9th Cir. 1991); see also R.J. Reynolds Tobacco Co. v. Star Scientific, Inc., 169 F. Supp.2d 452, 455 (M.D.N.C. 2001). The Federal Circuit has stated that in patent cases courts should follow the first-to-follow rule, whether or not the first action is a declaratory judgment, unless “considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise.” Genetech, Inc. v. Eli Lilly & Co., 998 F.2d 931, 937 (Fed. Cir. 1993) (overruled in part on other grounds by Wilton v. Seven Falls Co., 515 U.S. 277, 289 (1995)).

AGA’s earlier-filed declaratory judgment action is clearly the “first filed” action. First, the declaratory judgment action was filed well before NMT filed its Complaint for patent infringement in this Court. Second, the 1998 Action does not count for purposes determining which complaint was the “first filed.” The 1998 Action was dismissed without prejudice on December 1, 2003. No decision or ruling was entered by the court on the merits or lack of merit concerning NMT’s claims under the ’420 patent. The effect of a dismissal without prejudice was to render the proceedings a nullity and left the parties as if the action had never been brought. See Neverson v. Bissonnette, 261 F.3d 120, 126 (1st Cir. 2001). NMT cannot claim priority from the first suit because that suit was rendered a nullity by the Court’s Order of Dismissal. Because the declaratory judgment action and the present action involve the same parties, and the

same dispute, the Court should decline jurisdiction and allow the parties to proceed in Minnesota.

Circumstances justifying abrogation of the first-to-file rule typically are found in situations where one party races to the courthouse by filing a declaratory judgment action in a forum that is unrelated to the dispute. See Veryfine Prods., Inc. v. Phlo Corp., 124 F. Supp.2d 16, 22 (D. Mass. 2000). Neither of these conditions exists here. First, this is not a situation where there was a race to the courthouse. AGA filed its Declaratory Judgment action on October 13, 2004, after NMT made it clear to AGA that the Patent Office Board of Appeals' decision in the on-going reexamination was "an important step in [NMT's] infringement efforts against AGA." NMT then waited until December 7, 2004 to file its own complaint for patent infringement. The 8 week delay between when AGA filed the Declaratory Judgment action and when NMT filed the present action suggests that NMT had not contemplated bringing an imminent lawsuit and negates an inference that AGA was merely in a "race to the courthouse." See Northwest Airlines, Inc. v. Am. Airlines, Inc., 989 F.2d 1002, 1007 (8th Cir. 1993) (holding that six week delay before plaintiff filed its own lawsuit indicates that the first-filed action could not have been filed in anticipation of litigation.)

Second, since AGA is a Minnesota resident, Minnesota is not a forum unrelated to the dispute.

Furthermore, NMT was never lulled into not filing the present action by a promise by AGA to forego litigation.

## **II. IN THE ALTERNATIVE, THE COURT SHOULD TRANSFER THIS ACTION TO THE U. S. DISTRICT COURT FOR THE DISTRICT OF MINNESOTA.**

28 U.S.C. § 1404(a) allows a court, for the convenience of the parties, to transfer any civil action to any other district where it might have been brought. The decision to transfer a

case pursuant to § 1404 normally rests within the sound discretion of the trial court. See Workgroup Tech Corp. v. MGM Grand Hotel, 246 F. Supp.2d 102, 116 (D. Mass. 2003) (citing Codex Corp. v. Milgo Elec. Corp., 553 F.2d 735, 737 (1st Cir. 1977)). A defendant seeking transfer to a more convenient forum has a burden of proving that transfer is warranted. Nowak v. Tak How Invs., Ltd., 94 F.3d 708, 719 (1st Cir. 1996).

**A. THE U. S. DISTRICT COURT FOR THE DISTRICT OF MINNESOTA IS AN APPROPRIATE VENUE TO HEAR NMT'S COMPLAINT FOR PATENT INFRINGEMENT.**

A prerequisite to application of 28 U.S.C. § 1404(a) is that the transferee forum must be a forum where the civil action may have been brought. A civil action for patent infringement, such as this case, may be brought in the judicial district where the defendant resides. 28 U.S.C. § 1400(b) (2004). For the purposes of venue, a corporate defendant resides in any judicial district where it is subject to personal jurisdiction at the time the action is commenced. 28 U.S.C. § 1391(c). AGA is a Minnesota corporation, so it is indisputable that NMT's complaint for patent infringement could have been brought in the U. S. District Court for the District of Minnesota. Not only could the present action have been brought in Minnesota, but virtually the same dispute is pending there as well.

**B. THE PRESENT ACTION SHOULD BE TRANSFERRED TO THE U. S. DISTRICT COURT FOR THE DISTRICT OF MINNESOTA FOR THE CONVENIENCE OF THE PARTIES.**

Where each corporate party is located in a different state, the factor of convenience for the parties is generally not decisive. See Levinger v. Matthew Stuart & Co., 676 F. Supp. 437, 441 (D. R.I. 1988). Normally requiring either party to litigate in a remote district will cause inconvenience and expense. See Paradis v. Dooley, 774 F. Supp. 79, 82 (D. R.I. 1991). However, NMT cannot argue that it is unable to litigate in Minnesota, because it has consented

to Minnesota's jurisdiction by filing its own complaint for patent infringement against Cardis, Inc. in the Minnesota District Court. See Uffner v. La Reunion Francaise, S.A., 244 F.3d 38, 41 (1st Cir. 2001) ("[P]ersonal jurisdiction may be acquired through voluntary appearance").

While it is true that this Court has jurisdiction over AGA, that is not the issue for determining a question of venue transfer under 28 U.S.C. § 1404(a). The issue is whether the conveniences of the parties should outweigh the normal preference of the first-to-file rule. There is nothing to suggest that the convenience of the parties is best served by litigating in Massachusetts.

**C. THE PRESENT ACTION SHOULD BE TRANSFERRED TO THE U. S. DISTRICT FOR THE DISTRICT OF MINNESOTA FOR THE CONVENIENCE OF THE WITNESSES.**

This factor greatly weighs in favor of transferring this case to Minnesota. Where the issue of witness convenience is raised, "a mere statement of convenience or a claim that the greater number of witnesses reside in a particular forum is insufficient. The number of witnesses is not determinative. The critical factor is the content of witness testimony." See Coady v. Ashcraft & Gere, 996 F. Supp. 95, 101 (D. Mass. 1998), rev'd, 223 F.3d 1 (1st Cir. 2000) (emphasis added). Moreover, where a court order or the persuasion of an employer can secure the appearance of the witnesses regardless of location of the forum, the location of the witness diminishes in importance. Sigros v. Walt Disney World Co., 129 F.Supp.2d 56, 71 (D. Mass. 2001).

Here, both parties will likely have employees that can speak to the distribution of their respective devices at the time of trial. What will be even more crucial for AGA's case however, will be the availability of witnesses to testify about the most fundamental issues concerning AGA's own patents and the AGA devices now being accused of infringement. This testimony

can only be provided by Kurt and Curtis Amplatz, the named inventors on AGA's patents on the AMPLATZER<sup>®</sup> Septal Occluder. Both inventors are in the best position to testify how the AMPLATZER<sup>®</sup> device works, how it was created, and how the structure, function, and result achieved by the AGA products are very different from what is described and claimed in the '420 patent. Both inventors reside in the State of Minnesota. However, neither Kurt nor Curtis Amplatz is a current employee of AGA. Consequently, if this case is permitted to proceed to trial in Minnesota, AGA will have these witnesses available to testify on its behalf. If this case proceeds to trial in Massachusetts, however, AGA may be denied critical testimony from these inventors as they are former employees of AGA, have no obligation to appear to testify in Massachusetts and are beyond the subpoena powers of this Court.

Conversely, NMT's key witness, Dr. Marks, the inventor of NMT's CardioSEAL technology, will be available to appear at trial on behalf of NMT regardless where this case is tried, based upon his contractual agreement with NMT. Dr. Marks can be compelled to appear in Minnesota, in fact, based upon that agreement. Moreover, Dr. Marks is a named party to the declaratory judgment action, and therefore can be compelled by the Minnesota Court to appear.<sup>1</sup> Consequently, there is no prejudice to NMT if this Court allows this case to go forward in Minnesota.

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<sup>1</sup> It is worth noting that not all of the necessary parties are present in this case. Dr. Marks is a party to the Minnesota litigation, but not the present action. Where an exclusive licensee is suing to enforce a patent, the patent owner should be either voluntarily or involuntarily joined so that that accused infringer can avoid multiple lawsuits and liabilities. See *Evident Corp. v. Church & Dwight Co., Inc.*, 2005 U.S. App. LEXIS 3005, \* 7 (Fed. Cir. Feb. 22, 2005). Dr. Marks was a party to the 1998 Action, but not a party to the present action.

**CONCLUSION**

This Court should grant Defendant AGA Medical Inc.'s motion and dismiss this case in favor of the first-filed Declaratory Judgment action, or, in the alternative, transfer this case to the U. S. District Court for the District of Minnesota.

Respectfully submitted,

Dated: March 3, 2005

/s/ James T. Nikolai

Thomas C. O'Konski (BBO  
#378,265)

John L. Capone (BBO # 656150)  
Cesari and McKenna, LLP

88 Black Falcon Avenue  
Boston, Massachusetts 02210  
(617) 951-2500

James T. Nikolai (admitted pro hac  
vice)  
Nikolai & Mersereau, P.A.  
900 Second Avenue South, Suite 820  
Minneapolis, MN 55402  
(612)339-7461

**Attorneys for defendant  
AGA MEDICAL CORPORATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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NMT Medical, Inc.,

Plaintiff,

v.

Civil Action # 04-12565 NG

AGA Medical Corporation

Defendant.

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**DECLARATION OF JODI RAUS**

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I, Jodi Raus, hereby declare under penalty of perjury as follows:

1. I am the Director of Regulatory Affairs for AGA Medical Corporation (“AGA”) since the inception of the company 1997. I submit this declaration in support of AGA’s Motion to Dismiss, or, in the Alternative, to Transfer Venue to the U. S. District Court for the District of Minnesota.

2. AGA is a corporation organized and existing under the laws of the State of Minnesota, and runs its operations out of Golden Valley, Minnesota. AGA specializes in the development and manufacture of innovative medical devices. AGA has developed and patented the AMPLATZER® Septal Occluder, which was the first device approved in the United States for closure of congenital heart defects such as secundum atrial septal defects (“ASD”), which are holes in the wall between the right and left atria of the heart. AGA has also developed patented, and/or secured FDA approval for various other devices for treating other conditions.

3. AGA owns a number of U. S. Patents on medical devices for occluding congenital apertures in the body such as Atrial and Ventricular Septal Defects (ASD) and Patent Ductus Arteriosus (PDA). These patents include U. S. Patent Nos. 5,725,552; 5,846,261; 5,944,738; and

6,123,715. A true and correct copy of each of these patents is included as Exhibit A to this declaration.

4. AGA keeps the documents related to the conception, reduction-to-practice, FDA approval, and sales of AGA's patented products are all kept at AGA's Golden Valley offices.

5. Curtis Amplatz and Kurt Amplatz are named inventors on the above referenced patents owned by AGA. Neither Curtis Amplatz nor Kurt Amplatz are current employees of AGA and we have no control over either of them.

6. AGA's employees who would be able to testify regarding the manufacture, use, and sale of the AMPLATZER<sup>®</sup> Septal Occluder all reside in Minnesota.

7. NMT Medical, Inc. ("NMT") is a Massachusetts corporation having its principal place of business in Boston, Massachusetts. Attached as Exhibit B to this declaration is a true and correct copy of a print out from NMT's website professing that that:

NMT Medical, Inc. is a publicly traded company (Nasdaq symbol NMTI), based in Boston, Massachusetts, that designs, develops, and markets innovative medical devices for the minimally invasive (non-surgical) treatment of patients who have cardiac sources of embolic stroke.

8. Attached as Exhibit C to this declaration is a true and correct copy of a print out from NMT's website showing that NMT's CardioSEAL device purports to close Atrial Septal Defects.

9. Exhibit D to this declaration is a true and correct copy of a print out from NMT's website evidencing that NMT has conducted clinical trials for using the CardioSEAL device to occlude ASD at Abbot Northwestern Hospital in Minneapolis, MN. Exhibit E is a true and correct print out from NMT's website showing that the "CLOSURE I" clinical study is being conducted at United's John Nasseff Heart Hospital in Saint Paul, Minnesota.

10. Exhibit F is a true and correct copy of a list of “CardioSEAL trained physicians” in Minnesota printed out from NMT’s website.

11. Exhibit G is a copy of the Docket Sheet and Complaint filed in the U.S. District Court for the District of Minnesota in NMT Medical, Inc. et al v. Cardia, Inc., No. 04-cv-4200-JNE-JGL (D. Minn. filed Sept. 22, 2004).

12. Exhibit H is a true and correct copy of a print out of the web page <http://www.pediatriccardiology.yourmd.com/>, accessed on February 1, 2005. This website shows that Dr. Marks is licensed to practice pediatric cardiology in New Jersey.

13. Exhibit I is a true and correct copy of U. S. Patent 5,108,420 to Dr. Marks on an “Aperture Occlusion Device” issued on April 28, 1992 (“the ’420 patent”).

14. Exhibit J is a copy of a Licensing Agreement, dated April 15, 1996, by and between NMT and Dr. Lloyd A. Marks (hereinafter “Licensing Agreement”). This copy is from a print out from the Securities and Exchange Commission’s (“S.E.C.”) website. NMT submitted this copy of the Licensing Agreement in a filing with the S.E.C. Article II, Paragraph 1 of the Licensing Agreement grants NMT “an exclusive worldwide license to make and use and sell LICENSED PRODUCTS and the exclusive right to sublicense others to make, use, and sell LICENSED PRODUCTS.” Article I, Paragraph 1 defines the term “LICENSED PRODUCTS” to mean:

“[D]evices and method manufactured, used or sold by NITINOL and sublicenses of NITINOL which are covered by U. S. Patent No. 5,108,420 and/or the claims of any patent owned by MARKS for the COVERED INVENTIONS which is licensed by NITINOL hereunder.”

15. Article III, paragraph 1 of the Licensing Agreement requires NMT to pay Dr. Marks certain sums of money. In addition NMT granted Dr. Marks warrants to purchase shares

of NMT common stock pursuant to Article III, paragraph 1(h). The term “Net Sales Price” is defined in Article I, paragraph 4.

16. NMT was required by the Licensing Agreement to accomplish development activities relative to at least one Licensed Product. See Article III, paragraph 1(e) of Licensing Agreement. Dr. Marks promised to participate in these developmental activities, including animal experiments (Article III, paragraph 1(e)(ii)) and human clinical trials. (Article III, paragraph 1(e)(iv)).

17. Article V of the Licensing Agreement required Dr. Marks to make “Technical Information” available to NMT, including product information, specifications and drawings necessary or useful for the manufacture, use, sale and installation of Licensed Products. The term “Technical Information” is further defined by Article I, paragraph 3 of the Licensing Agreement.

18. Article VI, paragraph 1 concerns legal actions “against” any and all infringers of Licensed Patents. This paragraph requires Marks to cooperate with NMT in such actions.

19. Exhibit K of this declaration is a true and correct copy of the Complaint and Docket Sheet from Nitinol Medical Tech. v. AGA Medical Corp. No. 98-cv-12506-NG (D. Mass. filed Dec. 10, 1998). In the Complaint, NMT alleges that AGA infringes the ’420 patent.

20. Exhibit L of this declaration is a true and correct copy of an “Order re: Motion to Stay” filed in Nitinol Medical Tech. v. AGA Medical Corp. No. 98-cv-12506-NG (D. Mass. filed Dec. 10, 1998). The Court noted that at least two pieces of prior art were not before the U. S. Patent and Trademark Office during the prosecution of the ’420 patents. “Order re: Motion to Stay”, pg. 1.

21. Attached as Exhibit M to this declaration is a true and correct copy of the Order of Dismissal, dated December 1, 2003, dismissing NMT's Complaint without prejudice.

22. Attached as Exhibit N to this declaration are true and correct copies of the selected parts of the file wrapper of the reexamination proceedings before the U. S. Patent and Trademark Office showing that the Examiner repeatedly rejected the claims of the '420 as unpatentable in light of the Munster Patent. Exhibit O is a copy of the Board of Patent Appeals August 19, 2004 decision reversing the Examiner on very narrow grounds.

23. Attached as Exhibit P to this declaration is a true and correct copy of a press release issued by NMT on Tuesday, September 7, 2004. In this press release, John E. Ahern, President and CEO of NMT declared:

“[t]he Board of Appeals decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively.”

24. Exhibit Q to this declaration is a true and correct copy of a letter from Mr. Ahern to John W. Borg, the Interim CEO of AGA Medical Corporation. Mr. Ahern directly informs Mr. Borg that the Patent Office Board of Appeals reversed the examiner's rejection of the claims of the '420 patent and remanded the case back to the examiner consistent with the Board of Appeals' decision.

25. Exhibit R to this declaration is a true and correct copy of the Complaint for Declaratory Judgment filed on October 13, 2004 and the Docket Sheet for AGA Medical Corp. v. Nitinol Medical Technologies, Inc. et al 04-cv-4486-JMR-FLN (D. Minn. Oct. 13, 2004).

26. Before serving NMT and Dr. Marks, counsel for AGA notified NMT's counsel that it had filed a declaratory judgment action in Minnesota. A true and correct copy of the

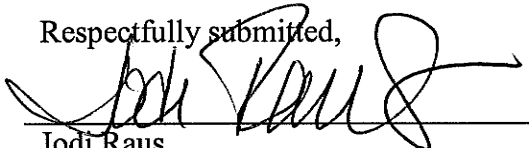
26. Before serving NMT and Dr. Marks, counsel for AGA notified NMT's counsel that it had filed a declaratory judgment action in Minnesota. A true and correct copy of the October 14, 2004 letter notifying counsel for NMT that AGA had filed a declaratory judgment action is included as Exhibit S.

27. Exhibits T & U are true and correct copies of Summons Returned Executed on NMT and Dr. Marks respectfully in AGA Medical Corp. v. Nitinol Medical Technologies, Inc. et al 04-cv-4486-JMR-FLN (D. Minn. Oct. 13, 2004).

28. A true and correct copy of the Complaint and Docket Sheet from the present action are attached as Exhibit V to this declaration.

29. As can be seen from a comparison of the Complaint for Declaratory Judgment shown in Exhibit R and the Complaint in Exhibit V, both the Minnesota Action and the present action involve substantially identical subject matter. The Complaint for Declaratory Judgment seeks a judgment declaring that the claims of the '420 patent that have survived reexamination are invalid and not infringed by AGA. The Complaint in Exhibit S seeks a judgment that the '420 patent is infringed by AGA. Intrinsic to a judgment of infringement is a finding that the claims of the '420 patent are valid. Thus, both cases seek to litigate the validity of the '420 patent, and whether the claims are infringed by AGA.

Dated: 03 March 2005

Respectfully submitted,  
  
Jodi Raus  
Director of Regulatory Affairs  
**AGA MEDICAL CORPORATION**

**EXHIBIT A - Part 1**



US00572552A

**United States Patent** [19]**Kotula et al.**[11] **Patent Number:** **5,725,552**[45] **Date of Patent:** **Mar. 10, 1998**[54] **PERCUTANEOUS CATHETER DIRECTED  
INTRAVASCULAR OCCLUSION DEVICES**[75] **Inventors:** **Frank Kotula**, Maple Grove; **Kurt Amplatz**; **Curtis Amplatz**, both of St. Paul, all of Minn.[73] **Assignee:** **AGA Medical Corporation**, Golden Valley, Minn.[21] **Appl. No.:** **647,712**[22] **Filed:** **May 14, 1996****Related U.S. Application Data**[63] **Continuation-in-part of Ser. No. 272,335, Jul. 8, 1994.**[51] **Int. Cl.<sup>6</sup>** ..... **A61B 17/08**[52] **U.S. Cl.** ..... **606/213; 606/151**[58] **Field of Search** ..... 606/191-200,  
606/213, 151, 1[56] **References Cited****U.S. PATENT DOCUMENTS**

3,874,388	4/1975	King et al. .	
4,007,743	2/1977	Blake .	
4,619,246	10/1986	Nielsen .....	606/200
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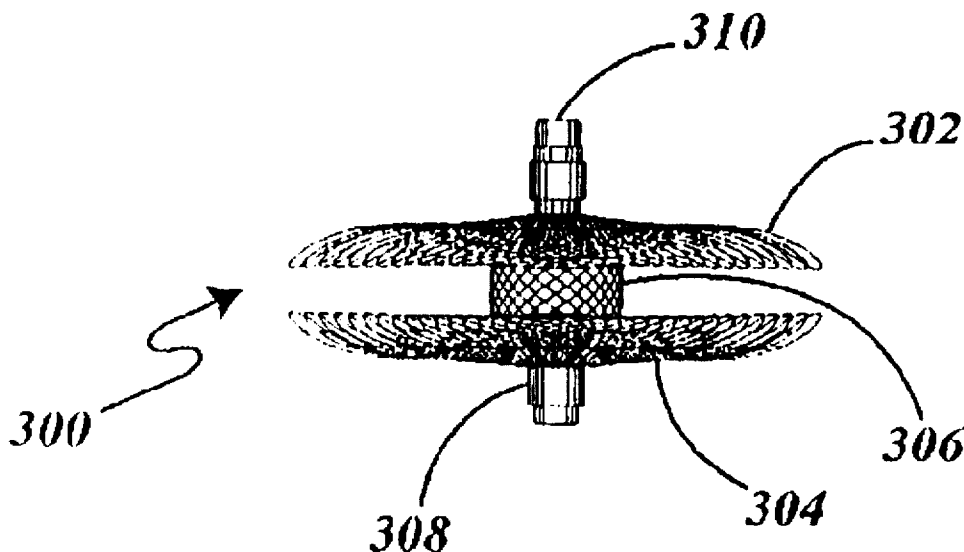
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*Primary Examiner*—Glenn K. Dawson  
*Attorney, Agent, or Firm*—Haugen & Nikolai, P.A.

[57] **ABSTRACT**

The present invention provides a method of forming a medical device and medical devices which can be formed in accordance with the method. In one embodiment, the method includes the steps of a) providing a metal fabric formed of a plurality of strands formed of a metal which can be heat treated to substantially set a desired shape; b) deforming the metal fabric to generally conform to a surface of a molding element; c) heat treating the metal fabric in contact with the surface of the molding element to substantially set the shape of the fabric in its deformed state; and d) removing the metal fabric from contact with the molding element. The resulting metal fabric will define a medical device which can be collapsed for passage through a catheter or the like for deployment in a channel of a patient's body. Medical devices made in accordance with this method can have varying structures.

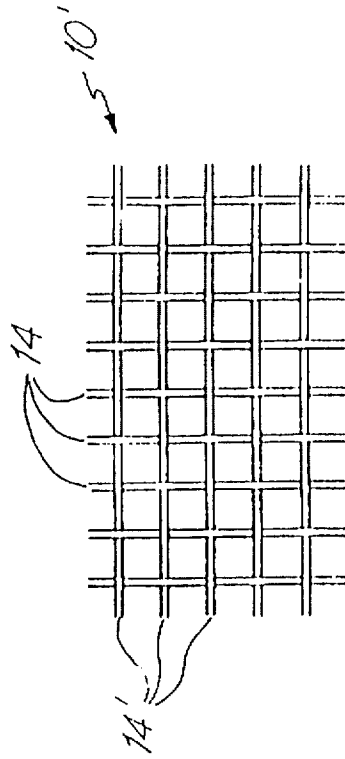
**12 Claims, 15 Drawing Sheets**

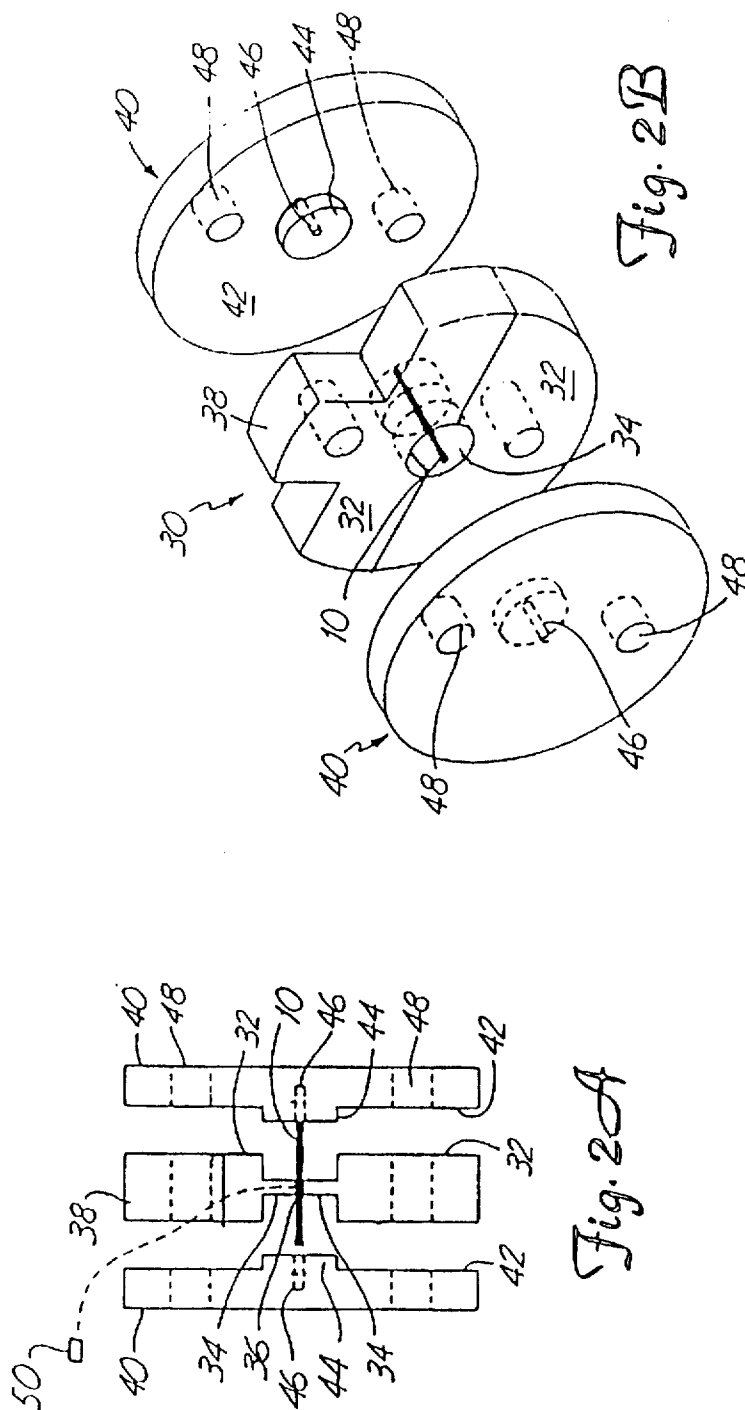
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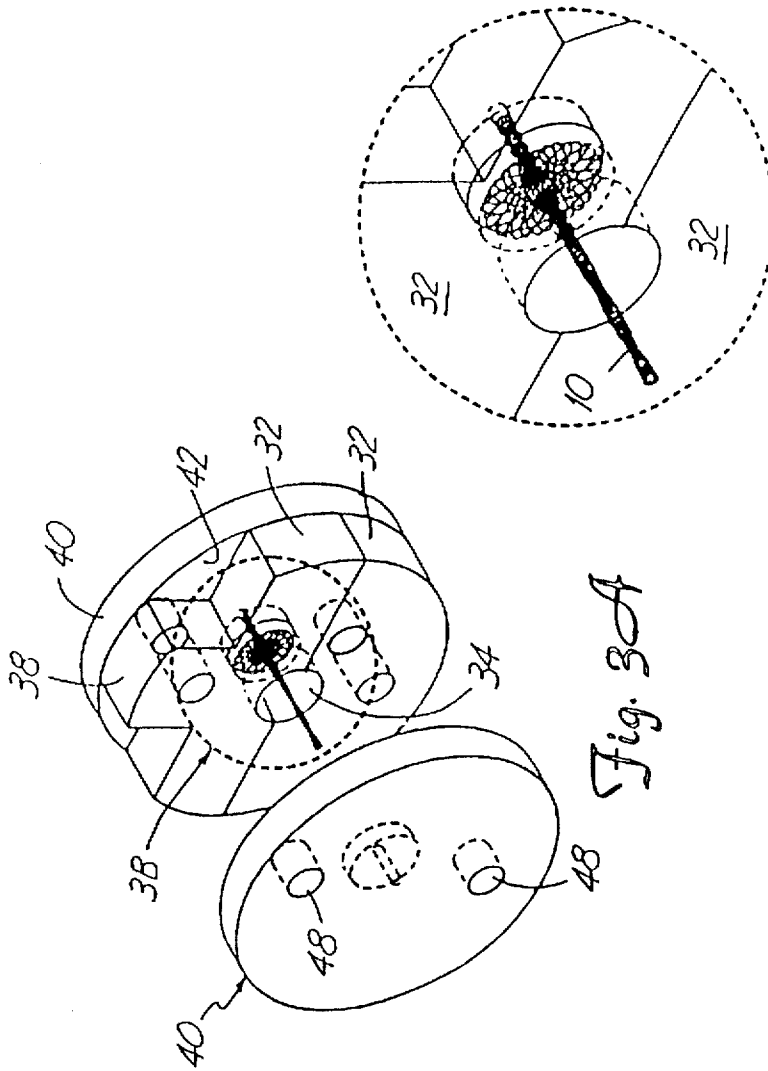


Fig. 3A

Fig. 3B

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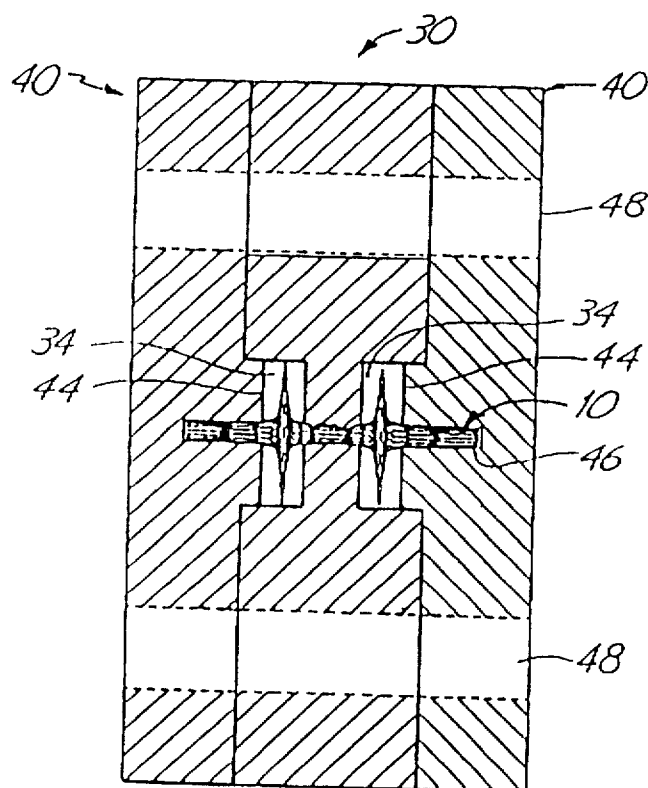


Fig. 4

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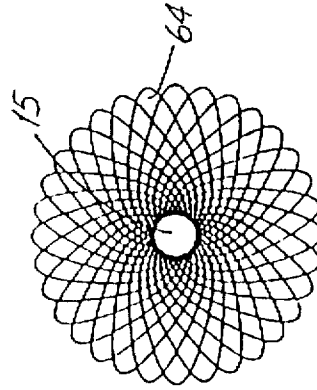


Fig. 5B

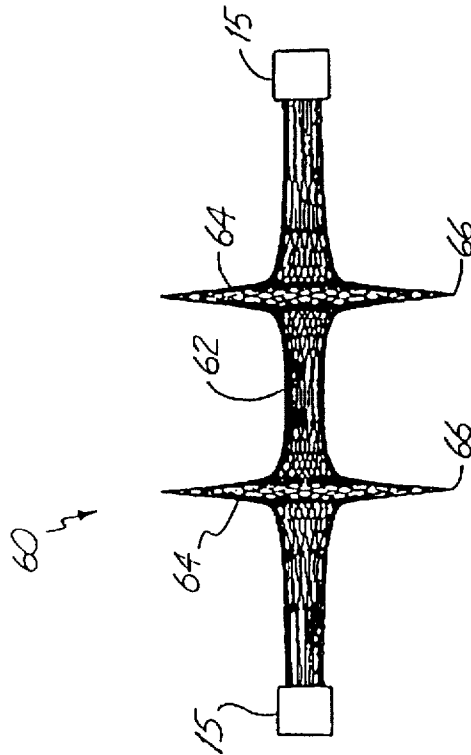


Fig. 5A

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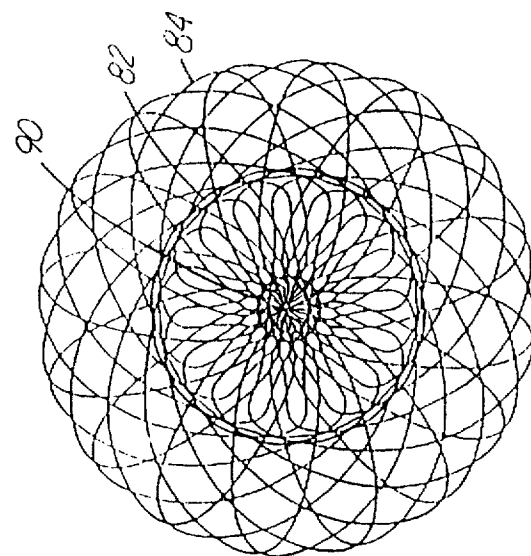


Fig. 6B

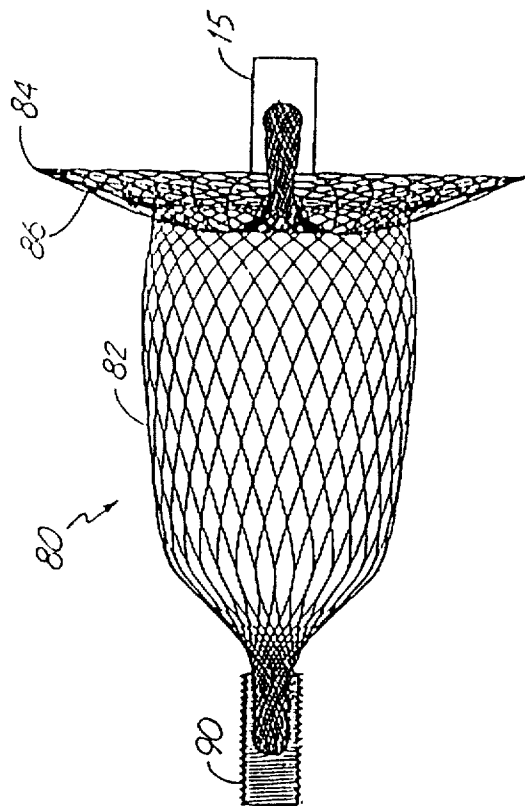


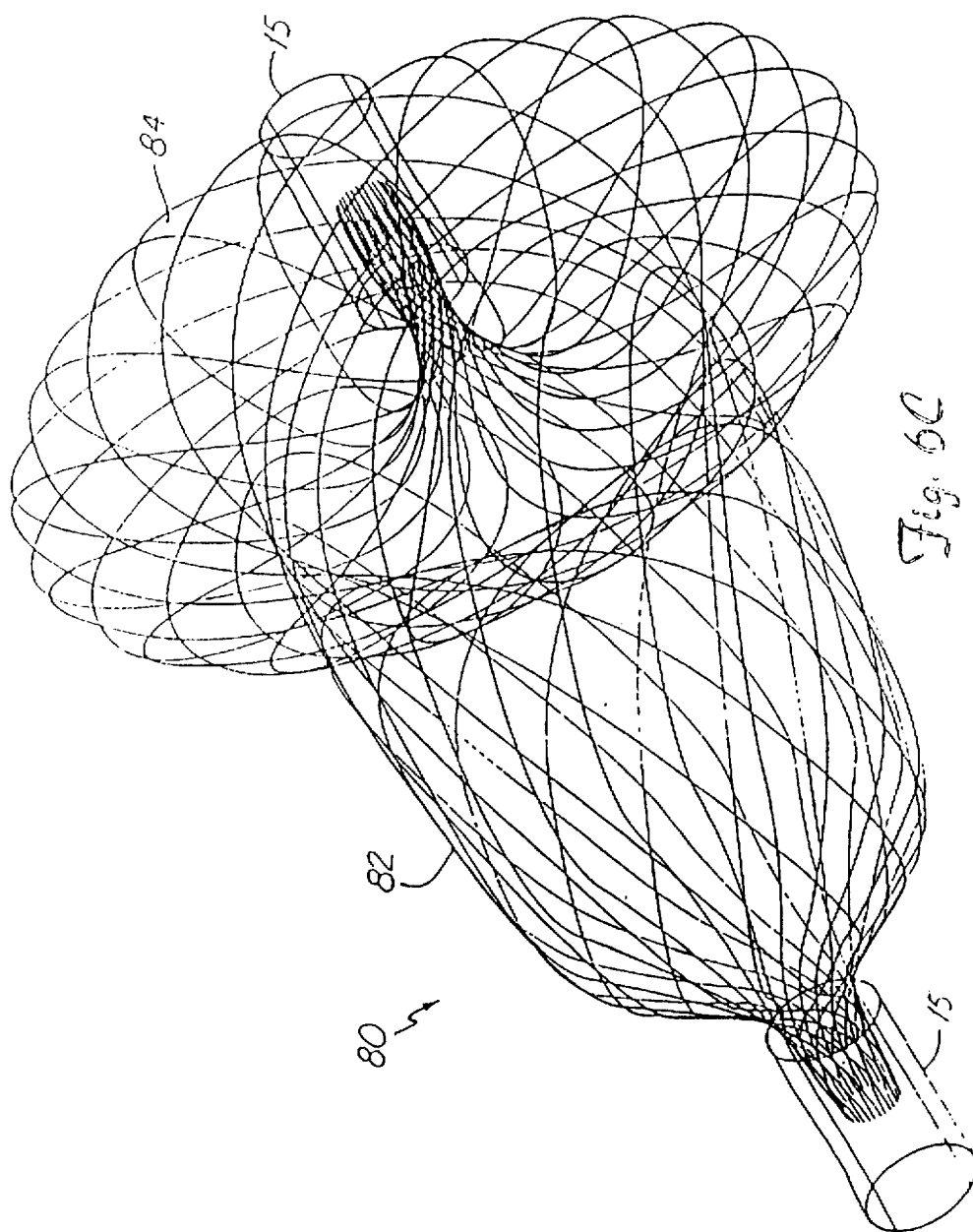
Fig. 6A

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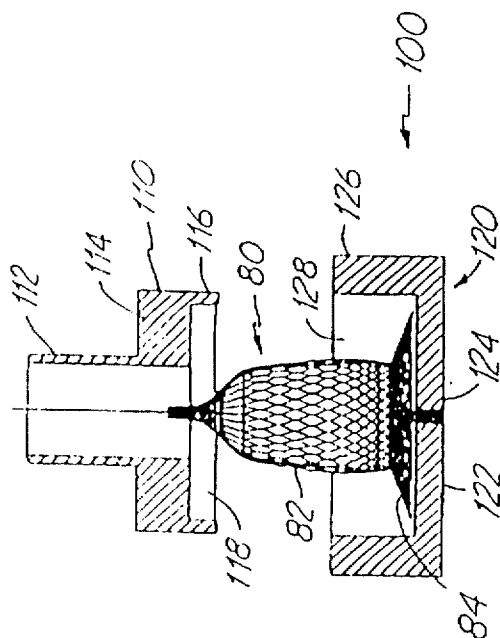


Fig. 1

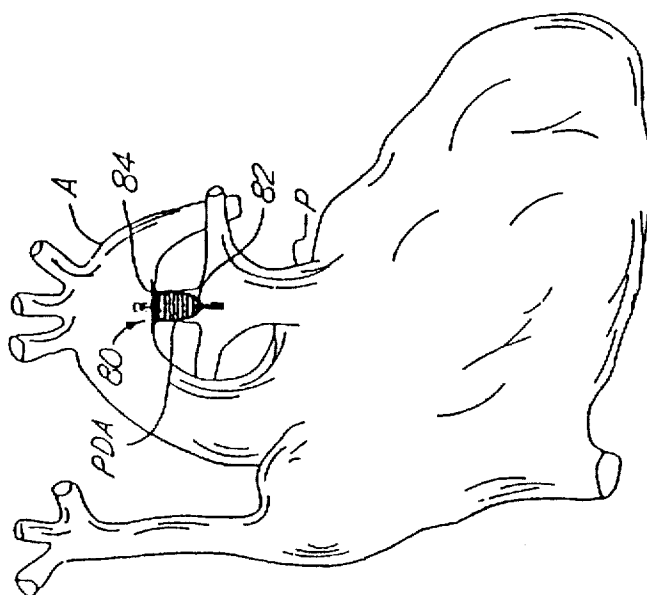
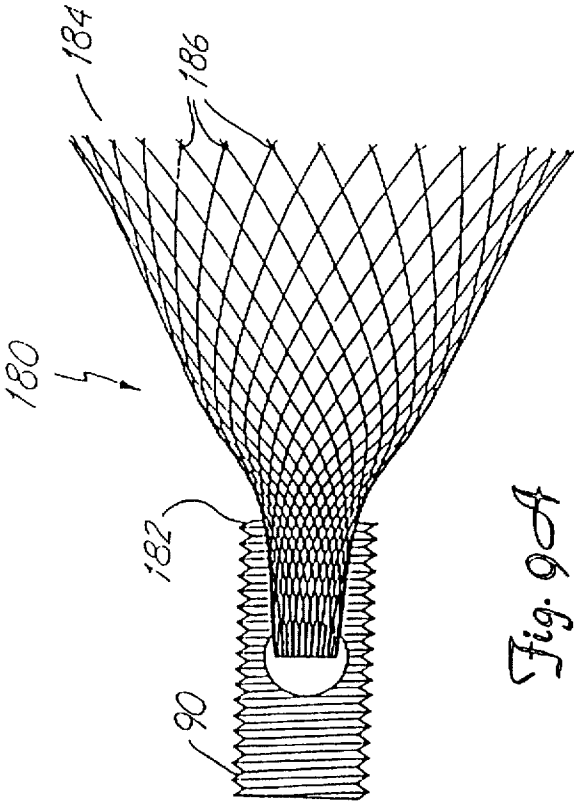
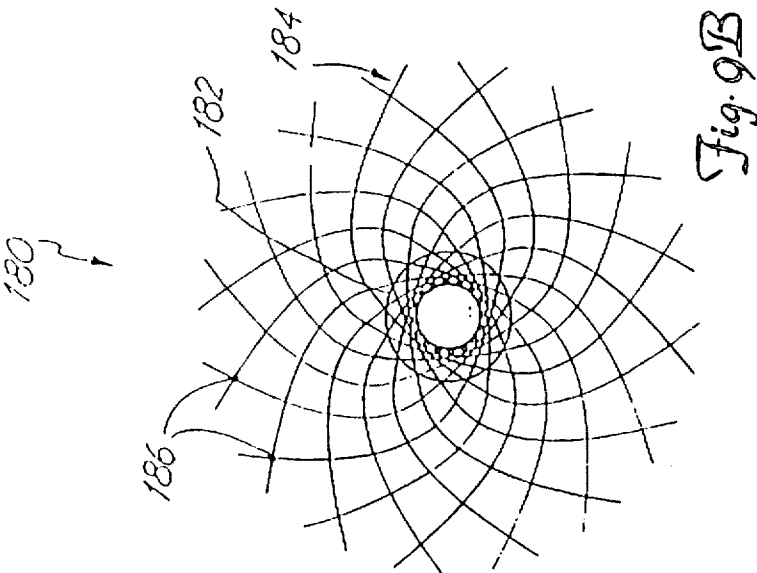


Fig. 8



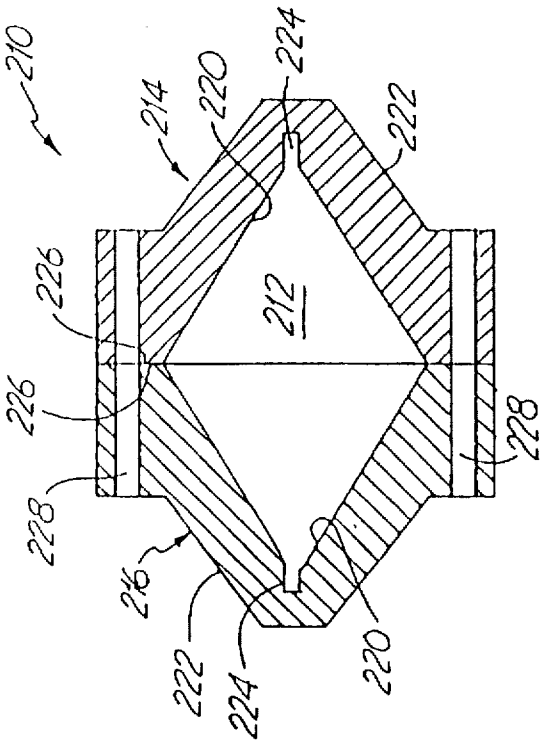


Fig. 10B

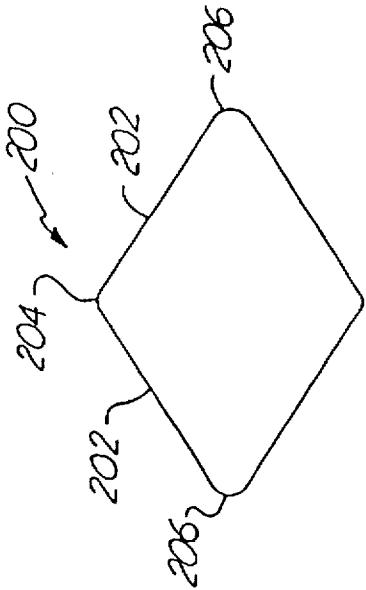


Fig. 10A

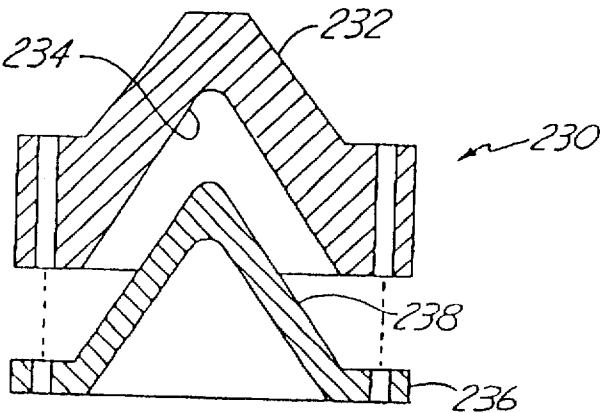


Fig. 10 C

Fig.11

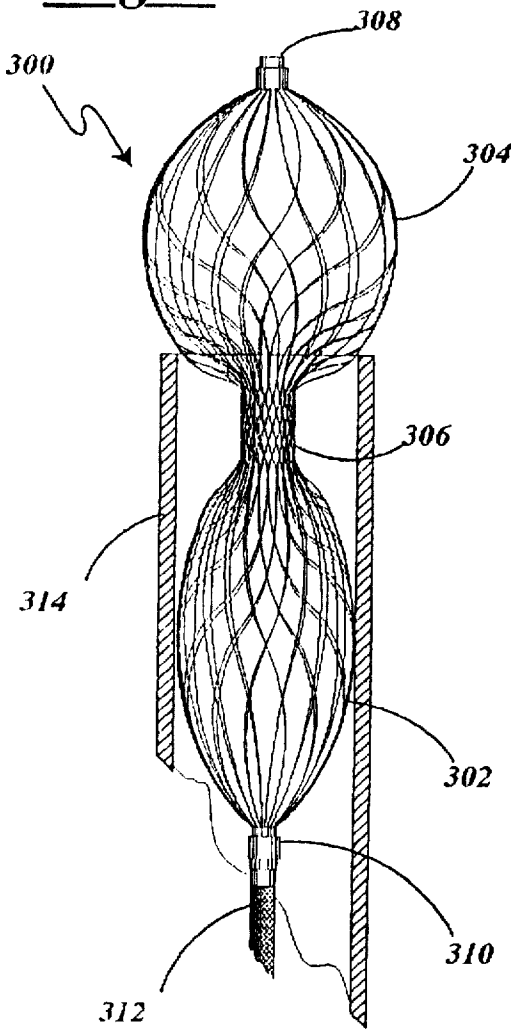
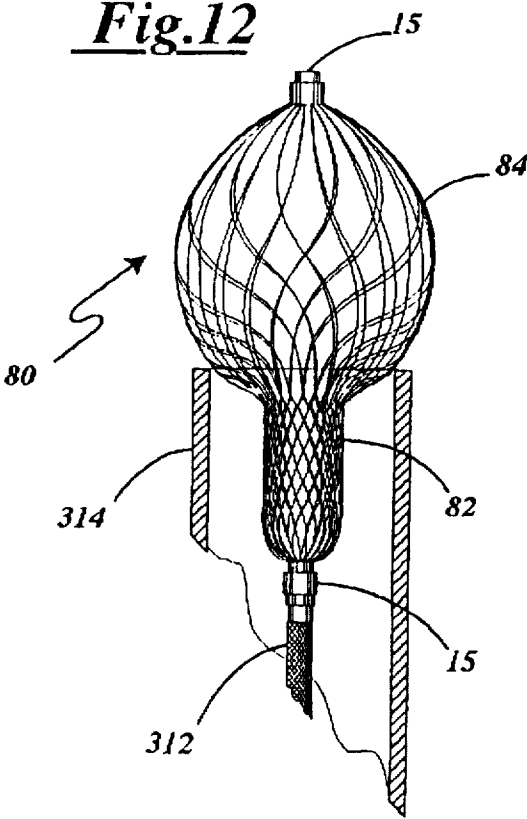


Fig.12



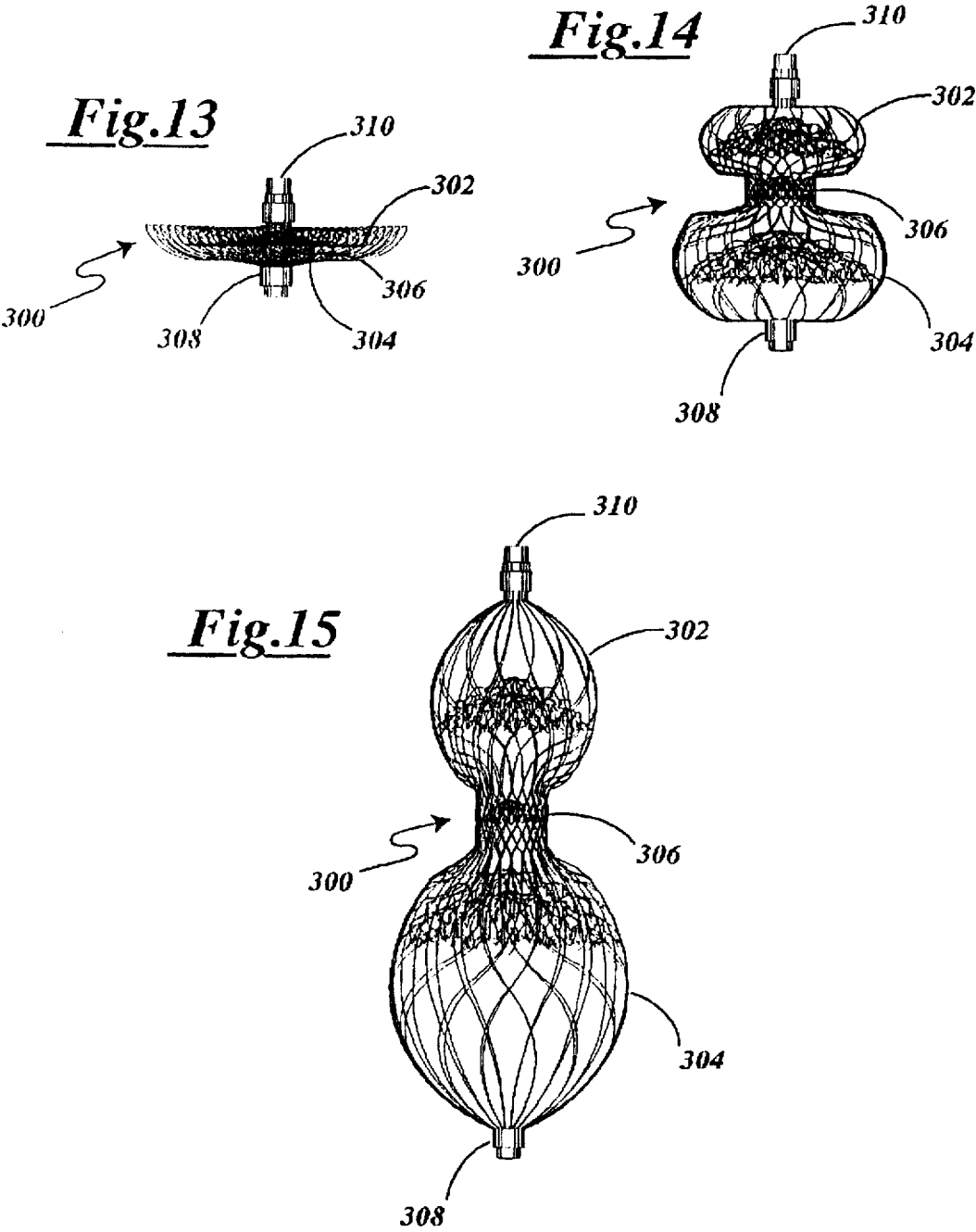


Fig.16

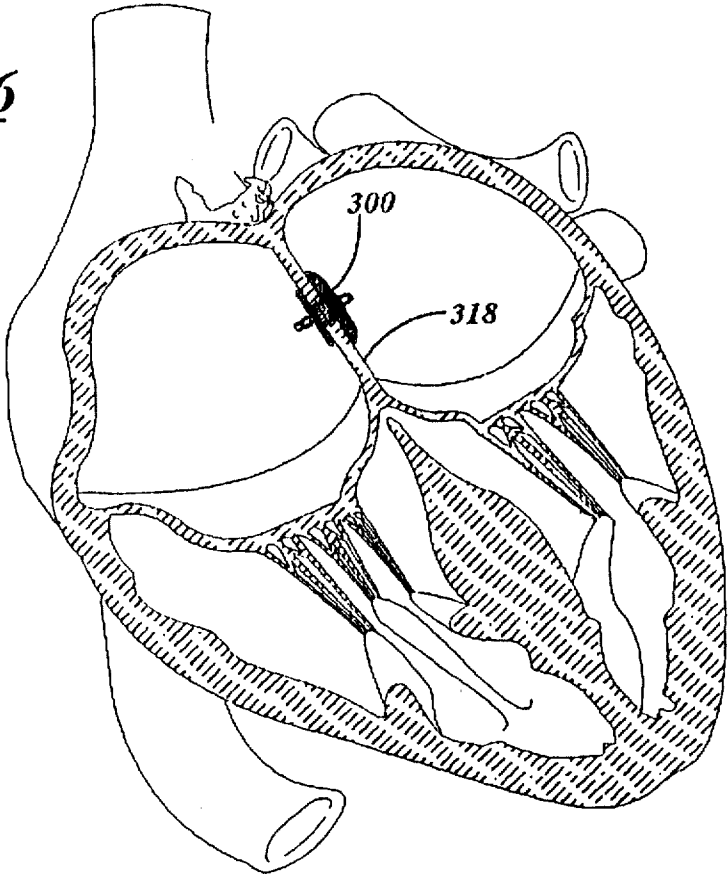


Fig.17

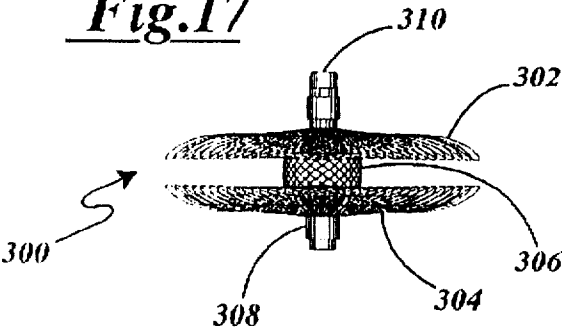
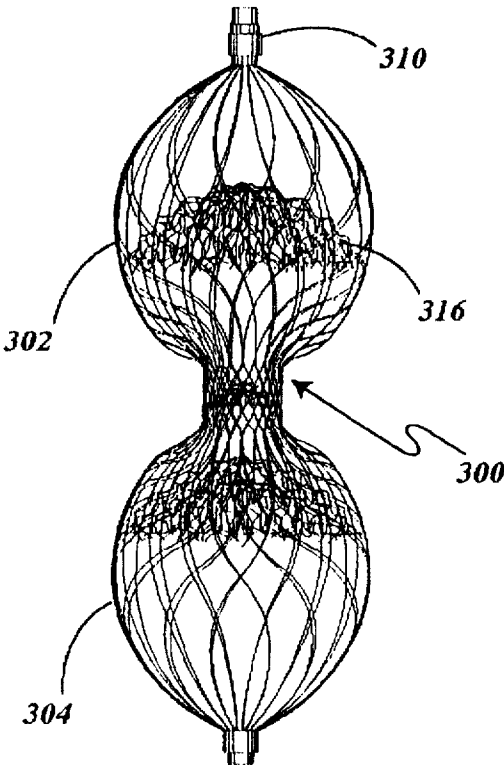


Fig.18



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## PERCUTANEOUS CATHETER DIRECTED INTRAVASCULAR OCCLUSION DEVICES

The present application is a Continuation-In-Part of application Ser. No. 08/272,335, filed on Jul. 8, 1994, and entitled "METHOD OF FORMING MEDICAL DEVICES; INTRAVASCULAR OCCLUSION DEVICES".

### BACKGROUND OF TEE INVENTION

#### I. Field of the Invention

The present invention generally relates to intravascular devices for treating certain medical conditions and, more particularly, relates to intravascular occlusion devices for Atrial Septal Defects (ASD) and Patent Ductus Arteriosus (PDA) treatment. The devices made in accordance with the invention are particularly well suited for delivery through a catheter or the like to a remote location in a patient's vascular system or in analogous vessels within a patient's body.

#### II. Description of the Related Art

A wide variety of intravascular devices are used in various medical procedures. Certain intravascular devices, such as catheters and guidewires, are generally used simply to deliver fluids or other medical devices to specific locations within a patient's body, such as a selective site within the vascular system. Other, frequently more complex, devices are used in treating specific conditions, such as devices used in removing vascular occlusions or for treating septal defects and the like.

In certain circumstances, it may be necessary to occlude a patient's vessel, such as to stop blood flow through an artery to a tumor or other lesion. Presently, this is commonly accomplished simply by inserting, for example, Ivalon particles (a trade name for vascular occlusion particles) and short sections of coil springs into a vessel at a desired location. These "embolization agents" will eventually become lodged in the vessel, frequently floating downstream of the site at which they are released before blocking the vessel. This procedure is often limited in its utility, in part, due to the inability to precisely position the embolization agents.

Balloon catheters similar to that disclosed by Landymore et al. in U.S. Pat. No. 4,836,204 have been used by physicians to temporarily occlude a septal defect until the patient stabilizes enough for open heart surgical techniques. Detachable balloon catheters are also used to block patients' vessels. When using such a catheter, an expandable balloon is carried on a distal end of a catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place.

Such balloon embolization is also prone to certain safety problems, though. For example, if the balloon is not filled enough, it will not be firmly fixed in the vessel and may rotate or drift downstream within the vessel to another location, much like the loose embolization agents noted above. In order to avoid this problem, physicians may overfill the balloons; it is not uncommon for balloons to rupture and release the resin into the patient's bloodstream.

Mechanical embolization devices, filters and traps have been proposed in the past, some of which are disclosed in King et al., U.S. Pat. No. 3,874,388; Das, U.S. Pat. No.

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5,334,217; and Marks, U.S. Pat. No. 5,108,420. The devices disclosed are pre-loaded into the introducer or delivery catheter and are not easily loadable by the physician. Further, during deployment of these devices, recapture into the delivery catheter is difficult if not impossible, thereby limiting the effectiveness of these devices.

Also, even if some of these devices prove to be effective occluders, they also tend to be rather expensive and time-consuming to manufacture. For example, some intravascular blood filters are formed of a plurality of specially-shaped legs which are adapted to fill the vessel and dig into the vessel walls. In making most such filters, the legs must be individually formed and then painstakingly attached to one another, frequently requiring attachment by hand, to assemble the final filter. Not only does this take significant skilled manpower, and hence increase the costs of such devices, the fact that each item must be made by hand tends to make quality control more difficult. This same difficulty and expense of manufacturing is not limited to such filters, but is experienced in many other intravascular devices as well.

When using these devices to occlude an ASD, the pressure and therefore the chance of dislodgment of the device increases with the square of the size of the communication. Consequently, these devices have to have a very large retention skirt. Often times, the position of the ASD dictates the size of the retention skirt. Hence, there is a need for an ASD occluder which may be made with a relatively small retention skirt. Also, the shape of the prior devices (for example squares, triangles, pentagons, hexagons and octagons) require a larger contact area, having corners which extend to the free wall of the atria. Each time the atria contracts (approximately 100,000 times per day), internal wires within the prior art devices are bent creating structural fatigue fractures in approximately 30 percent of all cases. Furthermore, the previous devices require a French 14-16 introducing catheter, making it impossible to treat children affected with congenital defects with these devices.

Accordingly, it would be advantageous to provide a reliable embolization device which is both easy to deploy through a 6-7 French catheter and which can be accurately placed in a vessel. It would also be desirable to provide a recoverable device for deployment in a vessel in a patient's body which is both economical and yields consistent, reproducible results.

### SUMMARY OF THE INVENTION

The present invention provides a reliable intravascular occlusion device which may be formed to treat, for example, Atrial Septal Defects (hereinafter ASD) and Patent Ductus Arteriosus (hereinafter PDA). When forming these intravascular devices from a resilient metal fabric a plurality of resilient strands is provided, with the wires being formed by braiding to create a resilient material which can be heat treated to substantially set a desired shape. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the braided fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The braided fabric so treated defines an expanded state of a medical device which can be deployed through a catheter into a channel in a patient's body.

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Further embodiments of the present invention also provide specific shapes for medical devices which may be made in accordance with the present invention to address predetermined medical procedures. Such devices of the invention are formed of a braided metal fabric and have an expanded configuration and a collapsed configuration. In use, a guide catheter can be positioned in a channel in a patient's body and advanced to position the distal end of the catheter adjacent a treatment site for treating a physiological condition. A medical device, formed in a predetermined shape, and made in accordance with the process outlined above, can be collapsed and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon, due to its memory property it will tend to substantially return to its expanded state adjacent the treatment site. In accordance with a first of these embodiments, a generally elongate medical device has a generally tubular middle portion and a pair of expanded diameter portions, with one expanded diameter portion positioned at either end of the middle portion. In another embodiment, the medical device is generally bell-shaped, having an elongate body having a tapered first end and a larger second end, the second end presenting a fabric disc which will be oriented generally perpendicular to an axis of a channel when deployed therein.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B each depict a metal fabric suitable for use with the invention;

FIG. 2A is exploded side view of a molding element having inserted a length of a metal fabric suitable for use in forming a medical device in accordance with the invention;

FIG. 2B is an exploded perspective view of the molding element shown in FIG. 2A;

FIG. 3A is a perspective view showing the molding element of FIGS. 2A and 2B in a partially assembled state;

FIG. 3B is a close-up view of a portion of the highlighted area of FIG. 3A showing the compression of the metal fabric in one of the molding element's cavities;

FIG. 4 is a cross-sectional view showing the molding element of FIGS. 2A and 2B in an assembled state, and having the metal fabric formed within the molding elements cavities;

FIG. 5A is a side view of a medical device in accordance with the invention;

FIG. 5B is an end view of a medical device in accordance with the invention;

FIGS. 6A-6C are a side view, an end view and a perspective view, respectively, of a medical device in accordance with another embodiment of the invention;

FIG. 7 is a side, cross sectional view of a molding element suitable for forming the medical device shown in FIGS. 6A-6C;

FIG. 8 is a schematic illustration showing the device of FIGS. 6A-6C deployed in a central shunt of a patient's vascular system;

FIG. 9A is a side view of a medical device in accordance with another alternate preferred embodiment;

FIG. 9B is an end view of the medical device shown in FIG. 9A;

FIG. 10A is a side view of one molding element suitable for forming the embodiment of FIGS. 9A and 9B;

FIG. 10B is a cross-sectional view of another molding element suitable for forming the embodiment of FIGS. 9A and 9B;

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FIG. 10C is a cross-sectional view of still another molding element suitable for forming the embodiment of FIGS. 9A and 9B;

FIG. 11 is an enlarged, partial sectional view of an ASD device shown stretched and partially extending out from the lumen of a delivery catheter;

FIG. 12 is a partial sectional view of a PDA device of the type shown in FIGS. 6A-6C, wherein the PDA device is shown stretched and partially extending out from the lumen of a delivery catheter;

FIG. 13 is an enlarged side elevational view of an ASD device, shown in its pre-shaped configuration;

FIG. 14 is a side elevational view of the ASD device of FIG. 13, shown slightly stretched and filled with polyester fibers;

FIG. 15 is a side elevational view of the ASD device of FIG. 13, shown stretched and filled with polyester fibers;

FIG. 16 is a partial sectional side elevational view of the ASD device of FIG. 13 shown positioned within an ASD of a patient's heart;

FIG. 17 is an enlarged side elevational view of an alternate ASD device, shown in its pre-shaped configuration; and

FIG. 18 is a side elevational view of the ASD device of FIG. 16, shown stretched and filled with polyester fibers.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a percutaneous catheter directed intravascular occlusion device for use in shunts in patients' bodies, such as vascular channels, urinary tracts, biliary ducts and the like. In forming a medical device via the method of the invention, a metal fabric 10 is provided. The fabric is formed of a plurality of wire strands having a predetermined relative orientation between the strands. FIGS. 1A and 1B illustrate two examples of metal fabrics which are suitable for use in the method of the invention.

In the fabric of FIG. 1A, the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid. Such tubular braids are well known in the fabric arts and find some applications in the medical device field as tubular fabrics, such as in reinforcing the wall of a guiding or diagnostic catheter. As such braids are well known, they need not be discussed at length here.

The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) may be adjusted as desired for a particular application. For example, if the medical device to be formed is to be used to occlude the channel in which it is placed, the pitch and pick of the fabric will tend to be higher than if the device is simply intended to filter bodily fluid passing therethrough.

For example, in using a tubular braid such as that shown in FIG. 1A to form a device such as that illustrated in FIGS. 5A and 5B, a tubular braid of about 4 mm in diameter with a pitch of about 50° and a pick of about 74 (per linear inch) would seem suitable for fabricating devices used in occluding channels on the order of about 2 mm to about 4 mm in inner diameter, as detailed below in connection with the embodiment of FIGS. 5A and 5B.

FIG. 1B illustrates another type of fabric which is suitable for use in the method of the invention. This fabric is a more

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conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like. In the woven fabric shown in FIG. 1B, there are also two sets 14 and 14' of generally parallel strands, with one set of strands being oriented at an angle, e.g. generally perpendicular (having a pick of about 90°), with respect to the other set. As noted above, the pitch and pick of this fabric (or, in the case of a knit fabric, the pick and the pattern of the knit, e.g. Jersey or double knits) may be selected to optimize the desired properties of the final medical device.

The wire strands of the metal fabric used in the present method should be formed of a material which is both resilient and which can be heat treated to substantially set a desired shape. Materials which are suitable for this purpose include a cobalt-based low thermal expansion alloy referred to in the field as Elgeloy, nickel-based high temperature high-strength "superalloys" commercially available from Haynes International under the trade name Hastelloy, nickel-based heat treatable alloys sold under the name Incoloy by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wires is that the wires retain a suitable amount of the deformation induced by the molding surface (as described below) when subjected to a predetermined heat treatment.

One class of materials which meet these qualifications are so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

One particularly preferred shape memory alloy for use in the present method is nitinol, an approximately stoichiometric alloy of nickel and titanium, which may also include other minor amounts of other metals to achieve desired properties. NiTi alloys such as nitinol, including appropriate compositions and handling requirements, are well known in the art and such alloys need not be discussed in detail here. For example, U.S. Pat. Nos. 5,067,489 (Lind) and 4,991,602 (Amplatz et al.), the teachings of which are incorporated herein by reference, discuss the use of shape memory NiTi alloys in guidewires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic—they are said to be "superelastic" or "pseudoelastic". This elasticity will help a device of the invention return to a present expanded configuration for deployment.

In forming a medical device in keeping with the invention, an appropriately sized piece of the metal fabric is cut from the larger piece of fabric which is formed, for example, by braiding wire strands to form a long tubular braid. The dimensions of the piece of fabric to be cut will depend, in large part, upon the size and shape of the medical device to be formed therefrom.

When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual wire strands will tend to return to their heat-set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more eco-

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nomical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device, as noted below.

In such untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of braid cut to form the device are constrained relative to one another. One method which has proven to be useful to prevent the braid from unraveling is to clamp the braid at two locations and cut the braid to leave a length of the braid having clamps (15 in FIG. 2) at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps 15 will hold the ends of the cut braid together and prevent the braid from unraveling.

Alternatively, one can solder, braze, weld or otherwise affix the ends of the desired length together (e.g. with a biocompatible cementitious organic material) before cutting the braid. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder.

The same problems present themselves when a flat sheet of fabric such as the woven fabric shown in FIG. 1B is used. With such a fabric, the fabric can be inverted upon itself to form a recess or depression and the fabric can be clamped about this recess to form an empty pocket (not shown) before the fabric is cut. If it is desired to keep the fabric in a generally flat configuration, it may be necessary to weld the junctions of the strands together adjacent the periphery of the desired piece of fabric before that piece is cut from the larger sheet. So connecting the ends of the strands together will prevent fabrics formed of untreated shape memory alloys and the like from unraveling during the forming process.

Once an appropriately sized piece of the metal fabric is obtained, the fabric is deformed to generally conform to a surface of a molding element. As will be appreciated more fully from the discussion below in connection with FIGS. 2-10, so deforming the fabric will reorient the relative positions of the strands of the metal fabric from their initial order to a second, reoriented configuration. The shape of the molding element should be selected to deform the fabric into substantially the shape of the desired medical device.

The molding element can be a single piece, or it can be formed of a series of mold pieces which together define the surface to which the fabric will generally conform. The molding element can be positioned within a space enclosed by the fabric or can be external of such a space, or can even be both inside and outside such a space.

In order to illustrate one example of how such a mold may be configured and how it may be used in accordance with the method of the invention, reference will be had to FIGS. 2-5. In FIGS. 2-4, the molding element 20 is formed of a number of separate pieces which can be attached to one another to complete the molding element 20. In using such a multi-piece molding element, the mold can be assembled about the cut length of fabric 10, thereby deforming the fabric to generally conform to the desired surface (or surfaces) of the molding element.

In the molding element illustrated in FIGS. 2-4, the metal fabric 10 is deformed to generally conform to a surface of the molding element 20, the molding element comprising a center section 30 and a pair of end plates 40. Turning first to the center section 30, the center section is desirably formed of opposed halves 32, 32 which can be moved away from one another in order to introduce the metal fabric 10 into the mold. Although these two halves 32, 32 are shown in the

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drawings as being completely separated from one another, it is to be understood that these halves could be interconnected, such as by means of a hinge or the like, if so desired. The opposed halves of the molding element 20 shown in the drawings of FIGS. 2 and 3 each include a pair of semi-circular recesses opposed on either side of a ridge defining a generally semi-circular opening. When the two halves are assembled in forming the device, as best seen in FIG. 3, the semi-circular openings in the opposed halves 32, 32 mate to define a generally circular forming port 36 passing through the center section 30. Similarly, the semi-circular recesses in the two halves together form a pair of generally circular central recesses 34, with one such recess being disposed on either face of the center section.

The overall shape and dimensions of the center section can be varied as desired; it is generally the size of the central recesses 34 and the forming port 36 which will define the size and shape of the middle of the finished device, as explained below. If so desired, each half 32 may be provided with a manually graspable projection 38. In the embodiment shown in the drawings, this projection 38 is provided at a location disposed away from the abutting faces of the respective halves. Such a manually graspable projection 38 will simply enable an operator to more easily join the two halves to define the recesses 34 and forming port 36.

The center section is adapted to cooperatively engage a pair of end plates 40 for forming the desired device. In the embodiment shown in FIGS. 2 and 3, the center section 30 has a pair of flat outer faces 39 which are each adapted to be engaged by an inner face 42 of one of the two end plates 40. Each end plate includes a compression disk 44 which extends generally laterally inwardly from the inner face 42 of the end plate. This compression disk 44 should be sized to permit it to be received within one of the central recesses 34 on either face of the center section 30. For reasons explained more fully below, each compression disk 44 includes a cavity 46 for receiving an end of the length of the metal fabric 10.

One or more channels 48 for receiving bolts and the like may also be provided through each of the end plates and through the center section 30. By passing bolts through these channels 48, one can assemble the molding element 20 and retain the metal fabric in the desired shape during the heat treatment process, as outlined below.

In utilizing the molding element 20 shown in FIGS. 2-4, a length of the metal fabric 10 can be positioned between the opposed halves 32 of the center section 30. In the drawings of the molding element 20 of FIGS. 2-4, the metal fabric 10 is a tubular braid such as that illustrated in FIG. 1A. A sufficient length of the tubular braid should be provided to permit the fabric to conform to the molding surface, as explained below. Also, as noted above, care should be taken to secure the ends of the wire strands defining the tubular braid in order to prevent the metal fabric from unraveling.

A central portion of the length of the metal braid may be positioned within one of the two halves of the forming port 36 and the opposed halves 32 of the center section may be joined to abut one another to restrain a central portion of the metal braid within the central forming port 36 through the center section.

The tubular braid will tend to have a natural, relaxed diameter which is defined, in large part, when the tubular braid is formed. Unless the tubular braid is otherwise deformed, when the wire strands are in their relaxed state they will tend to define a generally hollow tube having the predetermined diameter. The outer diameter of the relaxed

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braid may be, for example, about 4 mm. The relative size of the forming port 36 in the central section 30 of the molding element and the natural, relaxed outer diameter of the tubular braid may be varied as desired to achieve the desired shape of the medical device being formed.

In the embodiment shown in FIGS. 2 and 3, the inner diameter of the forming port 36 is optimally slightly less than the natural, relaxed outer diameter of the tubular braid 10. Hence, when the two halves 32, 32 are assembled to form the center section 30, the tubular braid 10 will be slightly compressed within the forming port 36. This will help ensure that the tubular braid conforms to the inner surface of the forming port 36, which defines a portion of the molding surface of the molding element 20.

If so desired, a generally cylindrical internal molding section (not shown) may also be provided. This internal molding section has a slightly smaller diameter than the inner diameter of the forming port 36. In use, the internal molding section is placed within the length of the metal fabric, such as by manually moving the wire strands of the fabric apart to form an opening through which the internal molding section can be passed. This internal molding section should be positioned within the tubular braid at a location where it will be disposed within the forming port 36 of the center section when the molding element is assembled. There should be a sufficient space between the outer surface of the interior molding section and the inner surface of the forming port 36 to permit the wire strands of the fabric 10 to be received therebetween.

By using such an internal molding section, the dimensions of the central portion of the finished medical device can be fairly accurately controlled. Such an internal molding section may be necessary in circumstances where the natural, relaxed outer diameter of the tubular braid 10 is less than the inner diameter of the forming port 36 to ensure that the braid conforms to the inner surface of that forming port. However, it is not believed that such an internal molding section would be necessary if the natural, relaxed outer diameter of the braid were larger than the inner diameter of the forming port 36.

As noted above, the ends of the tubular braid should be secured in order to prevent the braid from unraveling. Each end of the metal fabric 10 is desirably received within a cavity 46 formed in one of the two end plates 40. If a clamp (15 in FIG. 2) is used, the clamp may be sized to be relatively snugly received within one of these cavities 46 in order to effectively attach the end of the fabric to the end plate 40. The end plates can then be urged toward the center section 30 and toward one another until the compression disk 44 of each end plate is received within a central recess 34 of the center section 30. The molding element may then be clamped in position by passing bolts or the like through the channels 48 in the molding element and locking the various components of the molding element together by tightening a nut down onto such a bolt (not shown).

As best seen in FIG. 3A, when an end plate is urged toward the center section 30, this will compress the tubular braid 10 generally along its axis. When the tubular braid is in its relaxed configuration, as illustrated in FIG. 1A, the wire strands forming the tubular braid will have a first, predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis, as illustrated in FIG. 4. When the fabric is so deformed, the relative orientation of the wire strands of the metal fabric will change. When the molding element is finally assembled, the

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metal fabric will generally conform to the molding surface of this element.

In the molding element **20** shown in FIGS. 2-4, the molding surface is defined by the inner surface of the forming port, the inner surfaces of the central recess **34** and the faces of the compression disks **44** which are received within the recesses **34**. If an internal molding section is used, the cylindrical outer surface of that section may also be considered a part of the molding surface of the molding element **20**. Accordingly, when the molding element **20** is completely assembled the metal fabric will tend to assume a somewhat "dumbbell"-shaped configuration, with a relatively narrow center section disposed between a pair of bulbous, perhaps even disk-shaped end sections, as best seen in FIG. 4.

It should be understood that the specific shape of the particular molding element **20** shown in FIGS. 2-4 is intended to produce one useful medical device in accordance with the present method, but that other molding elements having different shape configurations could also be used. If a more complex shape is desired, the molding element may have more parts, but if a simpler shape is being formed, the molding element may have even fewer parts. The number of parts in a given molding element and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device as the molding element must define a molding surface to which the metal fabric will generally conform.

Accordingly, the specific molding element **20** shown in FIGS. 2-4 is simply intended as one specific example of a suitable molding element for forming one particular useful medical device. Additional molding elements having different designs for producing different medical devices are explained below in connection with, e.g., FIGS. 8 and 10. Depending on the desired shape of the medical device being formed, the shape and configuration of other specific molding elements can be readily designed by those of ordinary skill in the art.

Once the molding element **20** is assembled with the metal fabric generally conforming to a molding surface of that element, the fabric can be subjected to a heat treatment while it remains in contact with that molding surface. This heat treatment will depend in large part upon the material of which the wire strands of the metal fabric are formed, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface.

The time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire strands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a "superelastic" or "pseudoelastic" phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal when in its austenitic phase can be set. This will tend to "set" the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

Suitable heat treatments of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils,

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for example, are used in a number of medical applications, such as in forming the coils commonly carried around distal lengths of guidewires. A wide body of knowledge exists for forming nitinol in such medical devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention.

Briefly, though, it has been found that holding a nitinol fabric at about 500° C. to about 550° C. for a period of about 1 to about 30 minutes, depending on the softness or harness of the device to be made, will tend to set the fabric in its deformed state, i.e. wherein it conforms to the molding surface of the molding element. At lower temperatures the heat treatment time will tend to be greater (e.g. about one hour at about 350° C.) and at higher temperatures the time will tend to be shorter (e.g. about 30 seconds at about 900° C.). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors which will be well known to those skilled in this field.

Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. In the present invention, this can be accomplished by, for example, hooking electrodes to the clamps **15** carried at either end of the metal fabric illustrated in FIG. 5. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire molding element to the desired heat treating temperature in order to heat the metal fabric to the desired temperature.

After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in a deformed state. When the molding element **20** illustrated in FIGS. 2-4 is used, the bolts (not shown) may be removed and the various parts of the molding element may be disassembled in essentially the reverse of the process of assembling the molding element. If an internal molding section is used, this molding section can be removed in much the same fashion that it is placed within the generally tubular metal fabric in assembling the molding element **20**, as detailed above.

FIGS. 5A and 5B illustrate one embodiment of a medical device **60** which may be made using the molding element **20** of FIGS. 2-4. As discussed below, the device of FIG. 5 is particularly well suited for use in occluding a channel within a patient's body and these designs have particular advantages in use as vascular occlusion devices.

The vascular occlusion device **60** of FIG. 5A includes a generally tubular middle portion **62** and a pair of expanded diameter portions **64**. One expanded diameter portion is disposed at either end of the generally tubular middle portion **62**. In the embodiment shown in FIGS. 5A and 5B, the expanded diameter portions **64** include a ridge **66** positioned about midway along their lengths.

The relative sizes of the tubular middle section and the expanded diameter portions can be varied as desired. In this particular embodiment, the medical device is intended to be used as a vascular occlusion device to substantially stop the flow of blood through a patient's blood vessel. When the device **60** is deployed within a patient's blood vessel, as detailed below, it will be positioned within the vessel such that its axis generally coincides with the axis of the vessel. The dumbbell-shape of the present device is intended to limit the ability of the vascular occlusion device **60** to turn at an angle with respect to the axis of the blood vessel to

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ensure that it remains in substantially the same position in which the operator deploys it within the vessel.

In order to relatively strongly engage the lumen of the blood vessel, the maximum diameter of the expanded diameter portions 64 (which occurs along the middle ridge 66 in this embodiment) should be selected so that it is at least as great as the diameter of the lumen of the vessel in which it is to be deployed, and is optimally slightly greater than that diameter. When it is deployed within the patient's vessel, the vascular occlusion device 60 will engage the lumen at two spaced-apart locations. The device 60 is desirably longer along its axis than the dimension of its greatest diameter. This will substantially prevent the vascular occlusion device 60 from turning within the lumen at an angle to its axis, essentially preventing the device from becoming dislodged and tumbling along the vessel with blood flowing through the vessel.

The relative sizes of the generally tubular middle portion 62 and expanded diameter portion 64 of the vascular occlusion device 60 can be varied as desired for any particular application. For example, the outer diameter of the middle portion 62 may range between about one quarter and about one third of the maximum diameter of the expanded diameter portions 64 and the length of the middle portion 62 may comprise about 20% to about 50% of the overall length of the device. Although these dimensions are suitable if the device 60 is to be used solely for occluding a vascular vessel, it is to be understood that these dimensions may be varied if the device is to be used in other applications, such as where the device is intended to be used simply as a vascular filter rather than to substantially occlude the entire vessel or where the device is deployed in a different channel in a patient's body.

The aspect ratio (i.e., the ratio of the length of the device over its maximum diameter or width) of the device 60 illustrated in FIGS. 5A and 5B is desirably at least about 1.0, with a range of about 1.0 to about 3.0 being preferred and an aspect ratio of about 2.0 being particularly preferred. Having a greater aspect ratio will tend to prevent the device from rotating generally perpendicularly to its axis, which may be referred to as an end over end roll. So long as the outer diameter of the expanded diameter portions 64 of the device is large enough to seat the device fairly securely against the lumen of the channel in which the device is deployed, the inability of the device to turn end over end will help keep the device deployed precisely where it is positioned within the patient's vascular system or in any other channel in the patient's body. Alternatively, having expanded diameter portions which have natural, relaxed diameters substantially larger than the lumen of the vessels in which the device is deployed should also suffice to wedge the device into place in the vessel without undue concern being placed on the aspect ratio of the device.

The pick and pitch of the metal fabric 10 used in forming the device 60, as well as some other factors such as the number of wires employed in a tubular braid, are important in determining a number of the properties of the device. For example, the greater the pick and pitch of the fabric, and hence the greater the density of the wire strands in the fabric, the stiffer the device will be. Having a greater wire density will also provide the device with a greater wire surface area, which will generally enhance the tendency of the device to occlude a blood vessel in which it is deployed. This thrombogenicity can be either enhanced by, e.g. a coating of a thrombolytic agent, or abated, e.g. by a coating of a lubricious, anti-thrombogenic compound.

When the device is deployed in a patient's vessel, thrombi will tend to collect on the surface of the wires. By having a

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greater wire density, the total surface area of the wires will be increased, increasing the thrombotic activity of the device and permitting it to relatively rapidly occlude the vessel in which it is deployed. It is believed that forming the occlusion device 60 from a 4 mm diameter tubular braid having a pick of at least about 40 and a pitch of at least about 30° will provide sufficient surface area to substantially completely occlude a blood vessel of 2 mm to about 4 mm in inner diameter in a suitable period of time. If it is desired to increase the rate at which the device 60 occludes the vessel in which it is deployed, any of a wide variety of known thrombotic agents can be applied to the device.

FIGS. 6A-6C illustrate an alternative embodiment of a medical device in accordance with the present invention. This device 80 has a generally bell-shaped body 82 and an outwardly extending forward end 84. One application for which this device is particularly well suited is occluding defects known in the art as central shunts or patent ductus arteriosus (PDA). PDA is essentially a condition wherein two blood vessels, most commonly the aorta and pulmonary artery adjacent the heart, have a shunt between their lumens. Blood can flow directly between these two blood vessels through the shunt, compromising the normal flow of blood through the patient's vessels.

As explained more fully below in connection with FIG. 8, the bell-shaped body 82 is adapted to be deployed within the shunt between the vessels, while the forward end 84 is adapted to be positioned within the aorta to help seat the body in the shunt. The sizes of the body 82 and the end 84 can be varied as desired for differently sized shunts. For example, the body may have a diameter along its generally cylindrical middle 86 of about 10 mm and a length along its axis of about 25 mm. In such a device, the base 88 of the body may flare generally radially outward until it reaches an outer diameter equal to that of the forward end 84, which may be on the order of about 20 mm in diameter.

The base 88 desirably flares out relatively rapidly to define a shoulder tapering radially outwardly from the middle 86 of the body. When the device is deployed in a vessel, this shoulder will abut the lumen of the vessels being treated with higher pressure. The forward end 84 is retained within the vessel and urges the base 88 of the body open to ensure that the shoulder engages the wall of the vessel to prevent the device 80 from becoming dislodged from within the shunt.

As detailed above, in making a device of the invention it is desirable to attach the ends of the wire strands forming the metal fabric 10 to one another to prevent the fabric from unraveling. In the illustrations of FIGS. 6A-6C, a clamp 15 is used to tie together the ends of the wire strands adjacent the front end 84 of the device. It is to be understood that this clamp 15 is simply a schematic illustration, though, and that the ends could be attached in other ways, such as by welding, soldering, brazing, use of a biocompatible cementitious material or in any other suitable fashion.

The rearward ends of the wire strands are shown as being attached to one another by an alternative clamping means 90. This clamp 90 serves the same purpose as the schematically illustrated clamp 15, namely to interconnect the ends of the wires. However the clamp 90 also serves to connect the device 80 to a delivery system (not shown). In the embodiment shown, the clamp 90 is generally cylindrical in shape and has a recess for receiving the ends of the wires to substantially prevent the wires from moving relative to one another, and a threaded outer surface. The threaded outer surface is adapted to be received within a cylindrical recess

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(not shown) on a distal end of a delivery device and to engage the threaded inner surface of the delivery device's recess.

The delivery device (not shown) can take any suitable shape, but desirably comprises an elongate, flexible metal shaft having such a recess at its distal end. The delivery device can be used to urge the PDA occlusion device **80** through the lumen of a catheter for deployment in a channel of the patient's body, as outlined below. When the device is deployed out the distal end of the catheter, the device will still be retained by the delivery device. Once the proper position of the device **80** in the shunt is confirmed, the shaft of the delivery device can be rotated about its axis to unscrew the clamp **90** from the recess in the delivery means.

By keeping the PDA device **80** attached to the delivery means, the operator could still retract the device for repositioning if it is determined that the device is not properly positioned in the first attempt. This threaded attachment will also allow the operator to control the manner in which the device **80** is deployed out of the distal end of the catheter. As explained below, when the device exits the catheter it will tend to resiliently return to a preferred expanded shape which is set when the fabric is heat treated. When the device springs back into this shape, it may tend to act against the distal end of the catheter, effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp **90** can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled and the operator can control the deployment to ensure proper positioning.

APDA occlusion device **80** of this embodiment of the invention can advantageously be made in accordance with the method outlined above, namely deforming a metal fabric to generally conform to a molding surface of a molding element and heat treating the fabric to substantially set the fabric in its deformed state. FIG. 7 shows a molding element **100** which may be suitable for forming a PDA occlusion device **80** such as that shown in FIGS. 6A-6C.

The molding element **100** generally comprises a body portion **110** and an end plate **120**. The body portion **110** is adapted to receive and form the body **82** of the device **80** while the end plate is adapted to compress against the metal fabric to form the forward end **84**. The body portion **110** includes an elongate, generally tubular central segment **112** which is sized to receive the elongate body **82** of the device. The central segment **112** of the molding element **100** optimally has an internal diameter slightly less than the natural, relaxed outer diameter of the tubular braid of which the device is formed. This compression of the braid will help yield devices with reproducibly sized bodies **82**. The forward end of the body portion **110** includes a back plate **114** which has a generally annular sidewall **116** depending downwardly therefrom. The sidewall defines a recess **118** which is generally circular in shape.

The end plate **120** of the molding element **100** has a generally disc-shaped face **122**, which desirably has a clamp port **124** approximately centered therein for receiving a clamp **15** attached to the metal fabric, as noted above. The end plate also has an annular sidewall **126** which extends generally upwardly from the face **122** to define a generally cylindrical recess **128** in the end plate **120**. The sidewall **116** of the body portion **110** is sized to be received within the recess **128** of the end plate.

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In use, the metal fabric is placed in the molding element and the body portion **110** and the end plate **120** are brought toward one another. The inner face of the back plate **114** will engage the fabric and tend to urge it under compression generally radially outwardly. The fabric will then be enclosed generally within the recess **118** of the body portion and will generally conform to the inner surface of that recess. If one prevents the entire clamp **15** from passing through the clamp port **124**, the fabric will be spaced slightly away from the inner surface of the face **122**, yielding a slight dome shape in the forward end **84** of the device, as illustrated in FIGS. 6. Although the illustrated embodiment includes such a dome-shaped forward end, it is to be understood that the forward end may be substantially flat (except for the clamp **15**), which can be accomplished by allowing the clamp to be received entirely within the clamp port **124** in the end plate.

Once the fabric is compressed in the molding element **100** so that it generally conforms to the molding surface of the molding element, the fabric can be subjected to a heat treatment such as is outlined above. When the molding element is opened again by moving the body portion **110** and the end plate **120** away from one another again, the fabric will generally retain its deformed, compressed configuration. The device can then be collapsed, such as by urging the clamps **15**, **90** generally axially away from one another, which will tend to collapse the device toward its axis. The collapsed device **80** can then be passed through a catheter for deployment in a channel in a patient's vascular system.

FIG. 8 schematically illustrates how a medical device **80** generally as outlined above can be used to occlude a patent ductus arteriosus. In this case, there is a shunt, referred to as a PDA above, which extends between a patient's aorta **A** and the pulmonary artery **P**. The device **80** can be passed through the PDA, such as by keeping the device collapsed within a catheter (not shown), and the forward end **84** of the device can be allowed to elastically expand to substantially recover its thermally set, "remembered" shape from the heat treatment process, such as by urging the device distally to extend beyond the distal end of the catheter. This forward end **84** should be larger than the lumen of the shunt of the PDA.

The device can then be retracted so that the forward end **84** engages the wall of the pulmonary artery **P**. If one continues to retract the catheter, the engagement of the device with the wall of the PDA will tend to naturally pull the body portion **82** of the device from the catheter, which will permit the body portion to return to its expanded configuration. The body portion should be sized so that it will frictionally engage the lumen of the PDA's shunt. The device **80** will then be held in place by the combination of the friction between the body portion and the lumen of the shunt and the aortic blood pressure against the forward end **84** of the device. Over a relatively short period of time, thrombi will form in and on the device **80** and the thrombi will occlude the PDA. Those skilled in the art will appreciate that in order to speed up the occlusion of the PDA or ASD device, the device may be coated with a suitable thrombogenic agent, filled with a polyester fiber or braided with an increased number of wire strands.

FIGS. 9A and 9B are a side view and an end view, respectively, of yet another embodiment of the present invention. This device **180** can be used for a variety of applications in a patient's blood vessels. For example, if a fabric having a relatively high pick (i.e. where the wire density is fairly great) is used in making the device, the device can be used to occlude blood vessels. In other applications, it may serve as a filter within a channel of a

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patient's body, either in a blood vessel or in another channel, such as in a urinary tract or biliary duct. In order to further enhance or reduce the device's tendency to occlude the vessel, depending on the application of the device a suitable known anti-thrombogenic coating may be applied to the device.

This filter **180** has a generally conical configuration, tapering generally radially outwardly from its rearward end **182** to its forward end **184**. A length of the device adjacent its forward end is adapted to engage the walls of a lumen of a channel. The maximum diameter of the filter device **180** is therefore at least as large as the inner diameter of the channel in which it is to be positioned so that at least the forward end will engage the wall of the vessel to substantially lock the device in place.

Having a series of unsecured ends **185** of the wire strands adjacent the forward end of the device will assist in seating the device in the channel because the ends of the wires will tend to dig into the vessel wall slightly as the forward end of the device urges itself toward its fully expanded configuration within the vessel. The combination of the friction between the outwardly urging forward end of the device and the tendency of the wire ends to dig into the vessel walls will help ensure that the device remains in place where it is deployed rather than floating freely within a vessel to reach an undesired location.

The method in which the device **180** of the invention is deployed may vary depending on the nature of the physiological condition to be treated. For example, in treating an arterio-venous fistula, the device may be carefully positioned, as described above, to occlude the flow of blood at a fairly specific location. In treating other conditions (e.g. an arterio-venous malformation), however, it may be desired to simply release a number of these devices upstream of the malformation in a vessel having a larger lumen and simply allow the devices to drift from the treatment site to lodge in smaller vessels downstream.

The decision as to whether the device **180** should be precisely positioned at an exact location within the channel in a patient's body or whether it is more desirable to allow the device(s) to float to their final lodging site will depend on the size of the channels involved and the specific condition to be treated. This decision should be left to the individual operator to be made on a case-by-case basis as his or her experience dictates; there is no one right or wrong way to deploy the device **180** without regard to the conditions at hand.

In the embodiment shown in FIGS. **9A** and **9B**, the wall of the device extends generally linearly from a position adjacent the clamp **90** and the other end of the device, approximating a conical shape. Due to the presence of the clamp **90**, though, the end of the device immediately adjacent the clamp may deviate slightly from the cone shape, as indicated in the drawings. Alternatively, the wall may be curved so that the diameter of the device changes more rapidly adjacent the rearward end than it does adjacent its forward end, having an appearance more like a rotation of a parabola about its major axis than a true cone. Either of these embodiments should suffice in occluding a vessel with the device **180**, such as to occlude a vessel.

The ends of the wire strands at the rearward end **182** of the device are secured with respect to one another, such as by means of a threaded clamp **90** such as that described above in connection with FIGS. **6A-6C**. Portions of the wire strands adjacent the forward end **184** may also be secured against relative movement, such as by spot welding wires to

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one another where they cross adjacent the forward end. Such a spot weld is schematically illustrated at **186** in FIGS. **9A** and **9B**.

In the embodiment illustrated in FIGS. **9**, though, the ends of the wire strands adjacent the forward end **184** in the finished device need not be affixed to one another in any fashion. These strands are held in a fixed position during the forming process to prevent the metal fabric from unraveling before it is made into a finished device. While the ends of the wire strands adjacent the forward end remain fixed relative to one another, they can be heat treated, as outlined above. The heat treatment will tend to fix the shapes of the wires in their deformed configuration wherein the device generally conforms to a molding surface of the molding element. When the device is removed from contact with the molding element, the wires will retain their shape and tend to remain intertwined. Accordingly, when the device is released from contact with the molding element, even if the ends of the wires are released from any constraint the device should still substantially retain its shape.

FIGS. **10A-10C** illustrate three suitable molds for use in forming the filter **180** of FIGS. **9A** and **9B**. In FIG. **10A**, the molding element **200** is a single piece which defines a pair of generally conical portions abutting one another. In another similar embodiment (not shown), the molding element **200** may be generally ovoid, shaped not unlike an American football or a rugby ball. In the embodiment illustrated in FIG. **10A**, though, the molding element is a little bit less rounded. This molding element comprises two conical segments **202** which abut one another at their bases, defining a larger diameter at the middle **204** of the element which can taper relatively uniformly toward the ends **206** of the element **200**.

When the a tubular braid is used in forming this device, the tubular metal fabric may be applied to the molding element by placing the molding element within the tubular braid and clamping the ends of the braid about the molding element before cutting the braid to the desired length. In order to better facilitate the attachment of the clamps **90** to the ends of the tubular braid, the ends **206** of the molding element may be rounded, as shown, rather than tapering to a sharper point at the ends of the molding element. In order to ensure that the braid more closely conforms to the outer surface of the molding element **200**, i.e. the molding element's molding surface, the natural, relaxed diameter of the braid should be less than the maximum diameter of the element, which occurs at its middle **204**. This will place the metal fabric in tension about the middle of the element and, in combination with the clamps at the ends of the braid, cause the braid to generally conform to the molding surface.

FIG. **10B** illustrates an alternative molding element **210** for forming a device substantially as shown in FIGS. **9A** and **9B**. Whereas the molding element **200** is intended to be received within a recess in the metal fabric, such as within the lumen of a length of tubular braid, the molding element **210** has an internal cavity **212** adapted to receive the fabric. In this embodiment, the molding element may comprise a pair of molding sections **214**, **216** and these mold sections may be substantially identical in shape. Each of the molding sections **214**, **216** generally comprise a conical inner surface **220** defined by a wall **222**. Each section also may be provided with a generally cylindrical axial recess **224** for receiving a clamp **15** (or **90**) carried by an end of the metal fabric.

The two molding sections should be readily attached to one another with the larger, open ends **226** of the sections

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abutting one another. The mold sections can simply be clamped together, such as by providing a reusable jig (not shown) which can be used to properly position the sections 214, 216 with respect to one another. If so desired, bolt holes 228 or the like may be provided to allow a nut and bolt, or any similar attachment system, to be passed through the holes and attach the sections 214, 216 together.

In use, a suitably sized piece of a metal fabric, optimally a length of a tubular braid, is placed in the recess 212 of the molding element and the two molding sections 214, 216 are urged toward one another. The fabric should have a relaxed axial length longer than the axial length of the recess 212 so that bringing the sections toward one another will axially compress the fabric. This axial compression will tend to urge the wire strands of the braid radially outwardly away from the axis of the braid and toward engagement with the molding surface of the element 210, which is defined by the surface of the recess 212.

Once the metal fabric is deformed to generally conform to the molding surface of either molding element 200 or 210, the fabric can be heat treated to substantially set the shape of the fabric in its deformed state. If molding element 200 is used, it can then be removed from the interior of the metal fabric. If there is sufficient room between the resilient wire strands, the molding element can simply be removed by opening the web of wire strands and pulling the molding element out of the interior of the metal fabric. If molding element 210 is employed, the two molding sections 214, 216 can be moved away from one another and the molded fabric can be retrieved from the recess 212. Depending on the shape of the molding surface, the resulting formed shape may resemble either a pair of abutting hollow cones or, as noted above, a football, with clamps, welds or the like provided at either end of the shape.

This shape can then be cut into two halves by cutting the wires in a direction generally perpendicular to the shared axis of the cones (or the major axis of the ovoid shape) at a location about midway along its length. This will produce two separate filter devices 180 substantially as illustrated in FIGS. 9A and 9B. If the wire strands are to be joined adjacent the forward end of the device (such as by the weldments shown as 186 in FIGS. 9A and 9B), this can be done before the conical or ovoid shape is severed into two halves. Much the same net shape could be accomplished by cutting the metal fabric into halves while it is still carried about molding element 200. The separate halves having the desired shape could then be pulled apart from one another, leaving the molding element ready for forming additional devices.

In an alternative embodiment of this method, the molding element 200 is formed of a material selected to permit the molding element to be destroyed for removal from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material, such as glass. Once the material has been heat treated in contact with the molding surface of the molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The glass shards can then be removed from the enclosure of the metal fabric. The resultant shape can be used in its generally conical shape, or it can be cut into two separate halves to produce a device substantially as shown in FIGS. 9A and 9B.

Alternatively, the molding element 200 can be formed of a material which can be chemically dissolved, or otherwise

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broken down, by a chemical agent which will not substantially adversely affect the properties of the metal wire strands. For example, the molding element can be formed of a temperature-resistant plastic resin which is capable of being dissolved with a suitable organic solvent. The fabric and the molding element can be subjected to a heat treatment to substantially set the shape of the fabric in conformance with the surface of the molding element, whereupon the molding element and the metal fabric can be immersed in the solvent. Once the molding element is substantially dissolved, the metal fabric can be removed and either used in its current shape or cut into separate halves, as outlined above.

Care should be taken to ensure that the material selected to form the molding element is capable of withstanding the heat treatment without losing its shape, at least until the shape of the fabric has been set. For example, the molding element could be formed of a material having a melting point above the temperature necessary to set the shape of the wire strands, but below the melting point of the metal forming the strands. The molding element and metal fabric can then be heat treated to set the shape of the metal fabric, whereupon the temperature can be increased to substantially completely melt the molding element, thereby removing the molding element from within the metal fabric.

It should be understood that the methods outlined immediately above for removing the metal fabric 10 from the molding element 200 can be used in connection with other shapes, as well. Although these methods may not be necessary or desirable if the molding element is carried about the exterior of the metal fabric (such as are elements 30-40 of the molding element 20 of FIGS. 2-4), if the molding element or some portion thereof is enclosed within the formed metal fabric (such as the internal molding section of the molding element 20), these methods can be used to effectively remove the molding element without adversely affecting the medical device being formed.

FIG. 10C illustrates yet another molding element 230 which can be used in forming a medical device such as that illustrated in FIGS. 9A and 9B. This molding element comprises an outer molding section 232 defining a tapered inner surface 234 and an inner molding section 236 having an outer surface 238 substantially the same shape as the tapered inner surface 234 of the outer molding section. The inner molding section 236 should be sized to be received within the outer molding section, with a piece of the metal fabric (not shown) being disposed between the inner and outer molding sections. The molding surface of this molding element 230, to which the fabric will generally conform, can be considered to include both the inner surface 234 of the outer molding section and the outer surface 238 of the inner molding section. This molding element 230 can be used with a metal fabric which is in the form of a tubular braid. If such a fabric is used and a clamp 15 (not shown in this drawing) or the like is provided to connect the ends of the wire strands adjacent one end of the device, a recess (not shown) analogous to the cavity 46 in the face of the compression disk 44 of molding element 20 (FIGS. 2-4) can be provided for receiving the clamp.

However, the present molding element 230 can be used quite readily with a flat woven piece of metal fabric, such as is illustrated in FIG. 1B. In using such a fabric, a suitably sized and shaped piece of fabric is cut; in using the molding element 230 to produce a device 180 analogous to that shown in FIGS. 9A and 9B, for example, a generally disk-shaped piece of the metal fabric 10' can be used. The metal fabric is then placed between the two sections 232.

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236 of the molding element and the sections are moved together to deform the fabric therebetween. After heat treatment, the fabric can be removed and will retain substantially the same shape as it had when it was deformed between the two molding sections.

As can be seen by the discussion of the various molding elements 200, 210 and 230 in FIGS. 10A-10C, it should be clear that a number of different molding elements may achieve essentially the same desired shape. These molding elements may be received entirely within a closed segment of fabric and rely on tension and/or compression of the fabric to cause it to generally conform to the molding surface of the molding element, as with the element 200 of FIG. 10A. The molding element 210 of FIG. 10B substantially encloses the fabric within a recess in the mold and relies on compression of the fabric (in this case axial compression of a tubular braid) to deform the fabric to the desired configuration. Finally, the fabric may be compressed between two coating parts of the molding element to deform the fabric, such as between the two sections 232, 236 of molding element 230 in FIG. 10C. Any one or more of these techniques may be used in achieving a finished product having a desired shape.

FIGS. 11 and 13-15 illustrate alternate preferred embodiment of a medical device in accordance with the present invention for correcting an atrial septal defect (ASD). With reference to FIGS. 13 and 15, the device 300 in its relaxed, unstretched state has two disks 302 and 304 aligned in spaced relation, linked together by a short cylinder 306. It is proposed that this device 300 may also be well suited in occluding defects known in the art as patent foramen ovale (hereinafter PFO). ASD is a congenital abnormality of the atrial septum characterized by structural deficiency of the atrial septum. A shunt may be present in the atrial septum, allowing flow between the right and left atriums. In large defects with significant left to right shunts through the defect, the right atrium and right ventricle are volume overloaded and the augmented volume is ejected into a low-resistance pulmonary vascular bed.

Pulmonary vascular occlusive disease and pulmonary atrial hypertension develops in adulthood. Patients with secundum ASD with a significant shunt (defined as a pulmonary blood flow to systemic blood flow ratio of greater than 1.5) are operated upon ideally at five years of age or whenever a diagnosis is made in later years. With the advent of two dimensional echocardiography and Doppler color flow mapping, the exact anatomy of the defect can be visualized. The size of the defect will correspond to the selected size of the ASD device to be used.

The device 300, shown in its unconfined or relaxed state in FIG. 13, is adapted to be deployed within the shunt comprising an ASD or a PFO. For exemplary purposes, use of the device 300 in an ASD closure procedure will be described below. Turning first to the constructional features of the device 300, the ASD occluder 300 is sized in proportion to the shunt to be occluded. In the relaxed orientation, the metal fabric is shaped such that two disk like members 302 and 304 are axially aligned and linked together by a short cylindrical segment 306. The length of the cylindrical segment 306 preferably approximates the thickness of the atrial septum, and ranges between 2 to 20 mm. The proximal 302 and distal 304 disks preferably have an outer diameter sufficiently larger than the shunt to prevent dislodging of the device. The proximal disk 302 has a relatively flat configuration, whereas the distal disk 304 is cupped towards the proximal end slightly overlapping the proximal disk 302.

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The ends of this braided metal fabric device 300 are welded or clamped together with clamps 308 and 310 as described above to avoid fraying. Of course the ends may alternately be held together by other means readily known to those skilled in the art. The clamp 310 tying together the wire strands at the proximal end also serves to connect the device to a delivery system (see FIG. 11). In the embodiment shown, the clamp 310 is generally cylindrical in shape and has a recess for receiving the ends of the metal fabric to substantially prevent the wires comprising the woven fabric from moving relative to one another. The clamp 310 also has a threaded surface within the recess. The threaded recess is adapted to receive and engage the threaded distal end of a delivery device 312.

The ASD occlusion device 300 of this embodiment of the invention can advantageously be made in accordance with the method outlined above. The device 300 is preferably made from a 0.005 inches nitinol wire mesh. The braiding of the wire mesh may be carried out with 28 picks per inch at a shield angle of about 64 degrees using a Maypole braider with 72 wire carriers. The stiffness of the ASD device 300 may be increased or decreased by altering the wire size, the shield angle, the pick size, the number of wire carriers or the heat treatment process.

Those skilled in the art will recognize from the preceding discussion that the cavities of the mold must be shaped consistent with the desired shape of the ASD device. Also, it will be recognized that certain desired configurations may require that portions of the cavities be cammed. FIGS. 17 and 18 illustrate an ASD device having a modified configuration. The proximal disk 302 is a mirror image of distal disk 304. The distance separating the proximal and distal disks 302 and 304 is less than the length of the cylindrical segment 306. The cup shape of the disk, as illustrated in FIGS. 13, 16 and 17, ensures complete contact between the occlusion device 300 and the atrial septum. As such, a neo endocardium layer of endothelial forms over the occlusion device 300, thereby reducing the chance of bacterial endocarditis.

Referring next to FIGS. 11, 14-16 and 18 the use of the device will now be discussed in greater detail. The device may be delivered and properly placed using two dimensional echocardiography and Doppler color flow mapping. As indicated above, the delivery device 312 can take any suitable shape, preferably comprising an elongated flexible metal shaft similar to a conventional guidewire. The delivery device 312 is used to advance the ASD occlusion device 300 through the lumen of a small diameter cylindrical tube 314, such as a delivery catheter, for deployment. The ASD device 300 is loaded into the small diameter cylindrical tube 314 by stretching the same to put it in an elongated condition. The device may be inserted into the lumen of the tube 314 during the procedure or preassembled at a manufacturing facility, in that the devices of the present invention do not take on a permanent set when maintained in a compressed state.

From a femoral vein approach, the delivery catheter or tube 314 is passed across the ASD. The device 300 is advanced through the delivery catheter until the distal end 304 becomes unconstrained on exiting the end of the catheter, whereupon it assumes its disk-like shape in the left atrium. The delivery catheter 314 is then pulled back in the proximal direction across the ASD and the delivery device 312 is likewise pulled in a proximal direction, urging the distal disk 304 against the septum 318. The delivery catheter 314 is then further pulled away from the septum 318, allowing the proximal disk 302 to extend out of the delivery catheter 314, where it resiliently returns to its predefined expanded disk-like shape (see FIG. 15). In this manner, the

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ASD device 300 is positioned such that the distal disk 304 presses against one side of the septum 318 while the proximal disk 302 presses against the other side of the septum 318. In order to increase its occluding ability, the device can contain polyester fibers 316 (see FIGS. 15 and 18). In instances where the device is improperly deployed on a first try, the device 300 may be recovered by pulling the deliver device 312 proximally, thereby retracting the device 300 back into the delivery catheter 314 prior to a second attempt at positioning the device 300 relative to the defect.

When the ASD occluding device 300 is properly placed, the physician rotates the delivery device 312, unscrewing the delivery device 312 from the clamp 310 of the occluding device 300. The threads on the clamp 310 are such that the rotation of the delivery device 312 unscrews the delivery device 312 from the clamp 310 of the occluding device 300, rather than merely rotating the occluding device 300. As noted above in alternate embodiments, the threaded clamp can enable the operator to maintain a hold on the device during deployment, or enables the operator to control the spring action during deployment of the device to ensure proper positioning.

Generally, the method in accordance with the present invention further includes a method of treating a physiological condition of a patient. In accordance with this method, a medical device suitable for treating the condition, which may be substantially in accordance with one of the embodiments outlined above, is selected. For example, if a patent ductus arteriosus is to be treated, the PDA occlusion device 80 of FIGS. 6A-6C can be selected. Once the appropriate medical device is selected, a catheter may be positioned within a channel in patient's body to place the distal end of the catheter adjacent the desired treatment site, such as immediately adjacent (or even within) the shunt of the PDA.

Medical devices made in accordance with the method of the invention outlined above have a preset expanded configuration and a collapsed configuration which allows the device to be passed through a catheter (see FIG. 12). The expanded configuration is generally defined by the shape of the medical fabric when it is deformed to generally conform to the molding surface of the molding element. Heat treating the metal fabric substantially sets the shapes of the wire strands in the reoriented relative positions when the fabric conforms to the molding surface. When the metal fabric is then removed from the molding element, the fabric may define a medical device in its preset expanded configuration.

The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter. For example, the devices shown in FIGS. 5A-5B, 6A-6C, and 13 may have a relatively elongated collapsed configuration wherein the devices are stretched along their axes (see FIGS. 11 and 12). This collapsed configuration can be achieved simply by stretching the device generally along its axis, e.g. by manually grasping the clamps 15 and pulling them apart, which will tend to collapse the expanded diameter portions 64 of the device 60 inwardly toward the device's axis. The PDA occlusion device 80 of FIGS. 6 also operates in much the same fashion and can be collapsed into its collapsed configuration for insertion into the catheter by applying tension generally along the axis of the device. In this regard, these devices 60 and 80 are not unlike "Chinese handcuffs", which tend to constrict in diameter under axial tension.

Once the medical device is collapsed and inserted into the catheter, it may be urged along the lumen of the catheter

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toward the distal end of the catheter. This may be accomplished by using a guidewire or the like to abut against the device and urge it along the catheter. When the device begins to exit the distal end of the catheter, which is positioned adjacent the desired treatment site, it will tend to resiliently return substantially entirely to its preset expanded configuration. Superelastic alloys, such as nitinol, are particularly useful in this application because of their ability to readily return to a particular configuration after being elastically deformed to a great extent. Hence, simply urging the medical device out of the distal end of the catheter tend to properly deploy the device at the treatment site.

Although the device will tend to resiliently return to its initial expanded configuration (i.e. its shape prior to being collapsed for passage through the catheter), it should be understood that it may not always return entirely to that shape. For example, the device 60 of FIG. 5 is intended to have a maximum outer diameter in its expanded configuration at least as large as and preferably larger than, the inner diameter of the lumen in which it is to be deployed. If such a device is deployed in a vessel having a small lumen, the lumen will prevent the device from completely returning to its expanded configuration. Nonetheless, the device would be properly deployed because it would engage the inner wall of the lumen to seat the device therein, as detailed above.

If the device is to be used to permanently occlude a channel in the patient's body, such as the devices 60 and 80 described above may be, one can simply retract the catheter and remove it from the patient's body. This will leave the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means, such as when the threaded clamp 90 shown in FIGS. 6 and 9 are attached to a distal end of the delivery means, as explained above. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A collapsible medical device, comprising a plurality of metal strands woven into a tubular woven metal fabric having a proximal end and a distal end, each end having a means for securing each end attached to said tubular woven metal fabric, thereby gathering said strands and inhibiting unraveling of the strands, said tubular woven metal fabric having an expanded preset configuration shaped to create an occlusion of an abnormal opening in a body organ, said expanded preset configuration being in a shape of a bell and deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the woven metal fabric having a memory property whereby the medical device tends to return to said expanded preset configuration when unconstrained.

2. The medical device as recited in claim 1, wherein said means for securing each end has a threaded bore for rotational attachment to a delivery device.

3. The medical device as recited in claim 2, further including an occluding fiber retained within a hollow central portion formed by said tubular woven fabric.

4. The medical device as recited in claim 1, wherein the metal fabric is manufactured from an alloy selected from the

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group consisting of stainless steel, nickel-titanium, and cobalt-chromium-nickel.

5. The medical device as recited in claim 4, further including an occluding fiber retained within a hollow central portion formed by said tubular woven fabric.

6. The medical device as recited in claim 1, further including an occluding fiber retained within a hollow central portion formed by said tubular woven fabric.

7. A collapsible medical device, comprising: a tubular woven metal fabric including a plurality of braided strands and having a proximal end and a distal end, each end having a clamp attached to said metal fabric to thereby gather said strands together and inhibit unraveling of the strands, said metal fabric having a collapsed configuration for delivery through a channel in a patient's body and a generally dumbbell shaped expanded preset configuration for substantially creating an occlusion of an abnormal opening in a body organ, the metal fabric in its expanded configuration having two expanded diameter portions and a reduced diameter portion disposed between the two expanded diameter portions, each expanded diameter portion having an inner and outer wall, wherein the inner wall of at least one of the expanded diameter portions is generally concave.

8. The medical device as recited in claim 7, further including an occluding fiber retained within a hollow central portion formed by said generally dumbbell shaped expanded configuration.

9. A collapsible medical device, comprising a tubular woven metal fabric including a plurality of braided strands

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and having a proximal end and a distal end, each end having a clamp attached to said tubular woven metal fabric to thereby gather said strands together and inhibit the strands from unraveling, said tubular woven metal fabric having an expanded preset configuration shaped to create an occlusion of an abnormal opening in a body organ, said expanded preset configuration being deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, wherein the expanded preset configuration comprises two expanded diameter portions and a reduced diameter portion, said reduced diameter portion having a length approximating a thickness of a patient's atrial septum, the woven metal fabric having a memory property whereby the medical device tends to return to said expanded preset configuration when unconstrained.

10. The medical device as recited in claim 9, wherein said clamp has a threaded bore adapted for rotationally receiving a delivery device.

11. The medical device as recited in claim 9, further including an occluding fiber contained within a hollow center portion formed by said tubular woven metal fabric.

12. The medical device as recited in claim 9, wherein the metal fabric is manufactured from an alloy selected from the group consisting of stainless steel, nickel-titanium, and cobalt-chromium-nickel.

\* \* \* \* \*

**EXHIBIT A - Part 2**



US005846261A

**United States Patent** [19][11] **Patent Number:** **5,846,261****Kotula et al.**[45] **Date of Patent:** **\*Dec. 8, 1998**[54] **PERCUTANEOUS CATHETER DIRECTED OCCLUSION DEVICES**

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[75] Inventors: **Frank Kotula**, Maple Grove; **Kurt Amplatz**, St. Paul, both of Minn.

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[ \* ] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,725,552.

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[21] Appl. No.: **925,935**

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[22] Filed: **Sep. 8, 1997**

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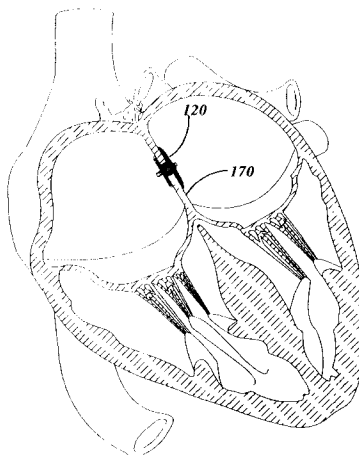
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[51] **Int. Cl.<sup>6</sup>** ..... **A61B 17/08**[52] **U.S. Cl.** ..... **606/213**[58] **Field of Search** ..... 606/213, 215, 606/216, 217, 151, 153, 191–198, 199, 200; 604/167, 281; 600/32; 128/899*Primary Examiner*—Michael Buiz*Assistant Examiner*—Vikki Trinh*Attorney, Agent, or Firm*—Haugen and Nikolai, P.A.[56] **References Cited**[57] **ABSTRACT****U.S. PATENT DOCUMENTS**

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A collapsible medical device and associated methods for occluding an abnormal opening in, for example, a body organ, wherein the medical device is shaped from a heat treatable metal fabric. The metal fabric is formed from a plurality of metal strands and is heat treated within a mold in order to substantially set a desired shape of the device. The medical device includes a fastener for attaching to the end of a guide wire or delivery catheter, wherein the shape of the medical device is formed such that the fastener is attached to the metal fabric within a recess formed in the shape of the medical device. A medical device having a preselected shape is delivered through a catheter or the like for deployment in a desired channel or opening in a patient's body. The medical device may be shaped, for example, to occlude an ASD, PDA, or a VSD.

**18 Claims, 10 Drawing Sheets**

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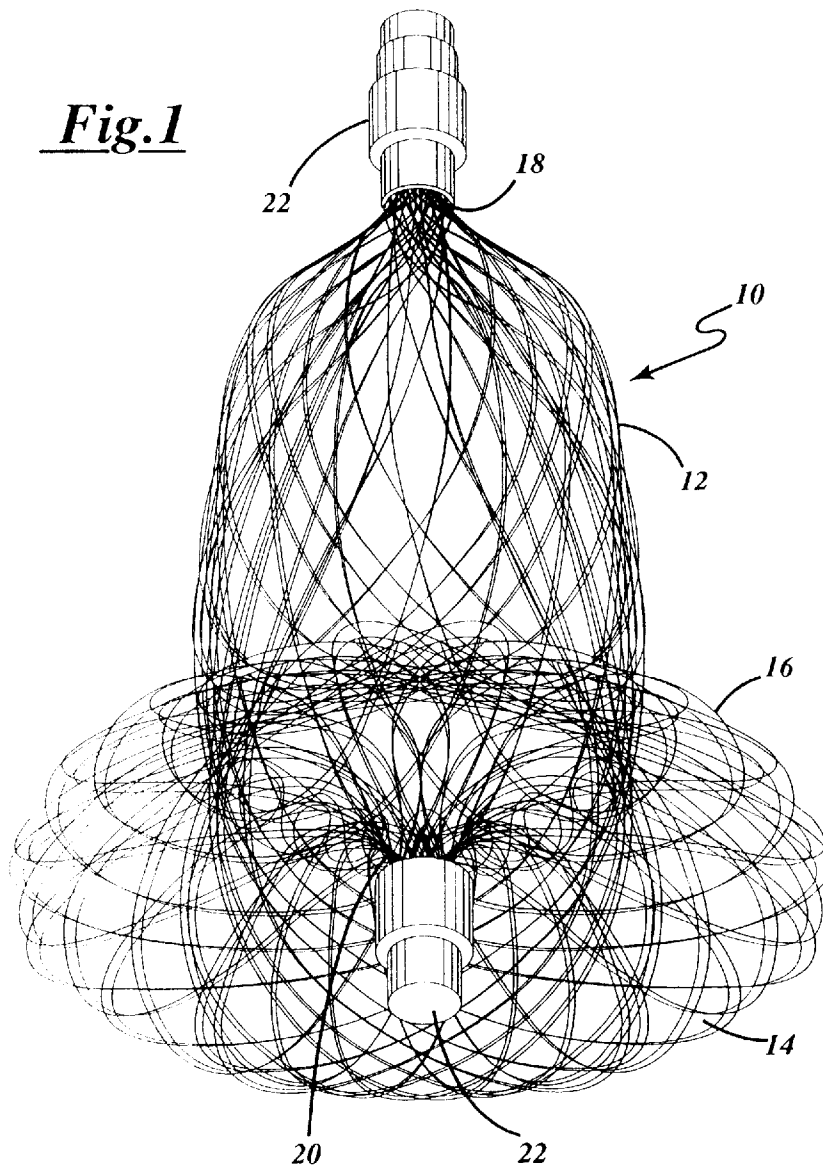
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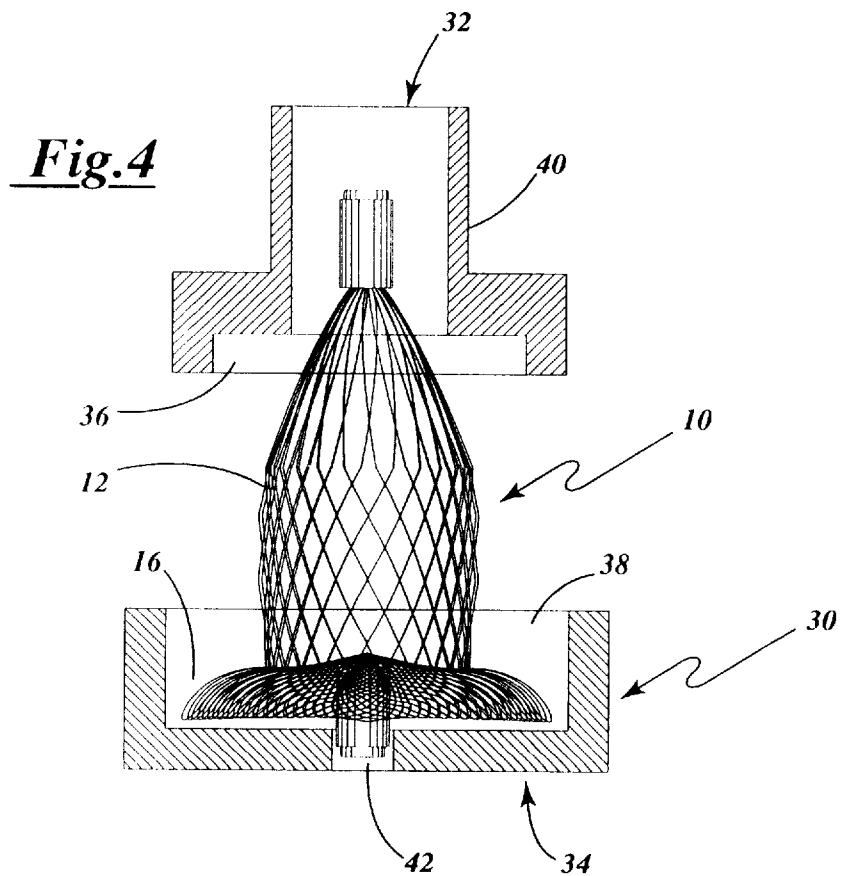
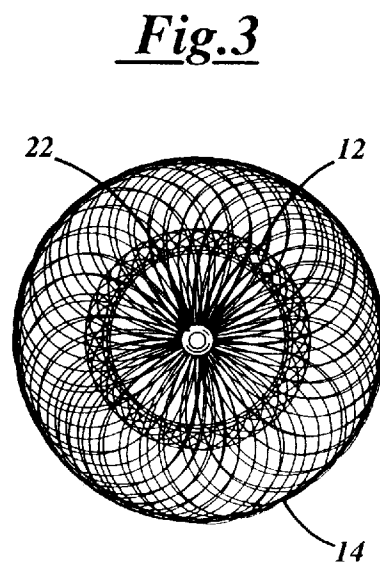
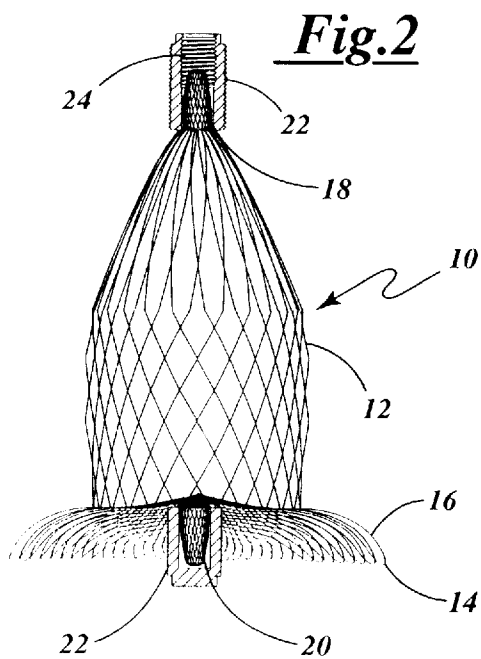
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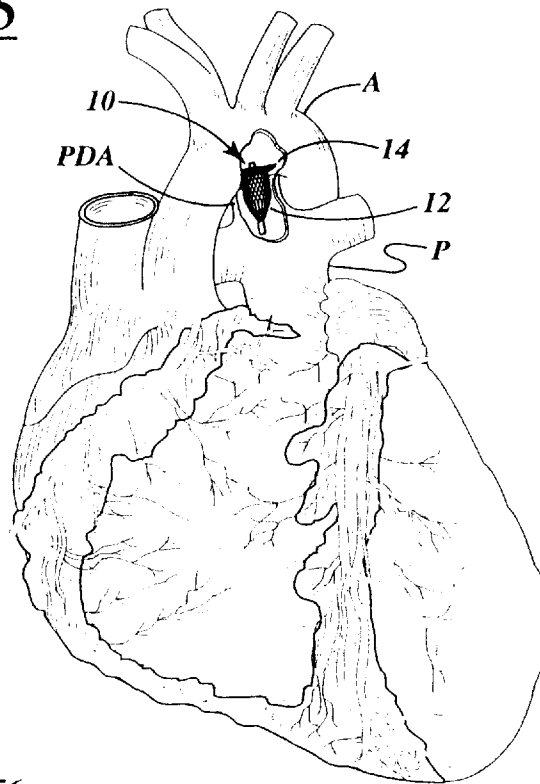
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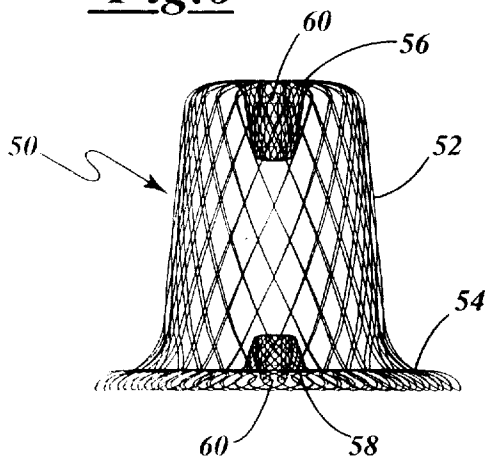




**Fig.5**



**Fig.6**



**Fig.7**

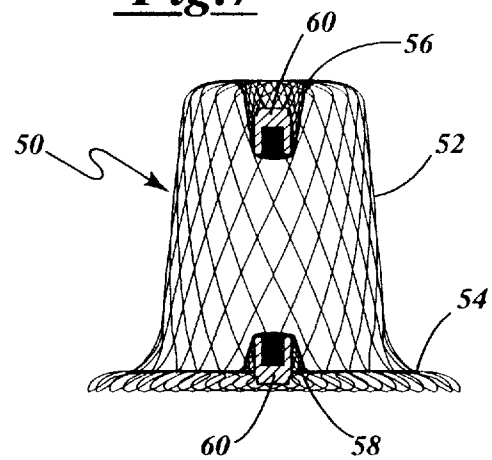


Fig.8

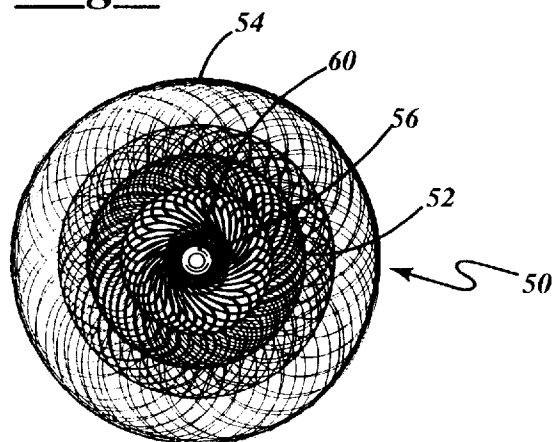


Fig.9

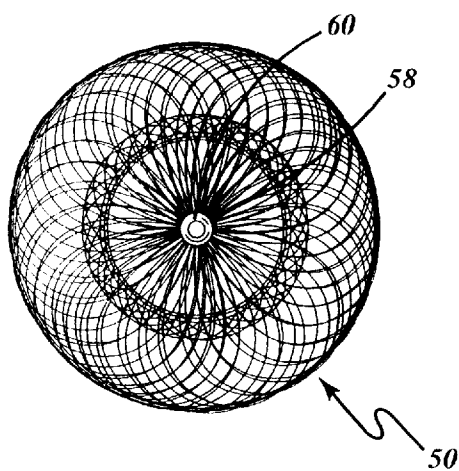
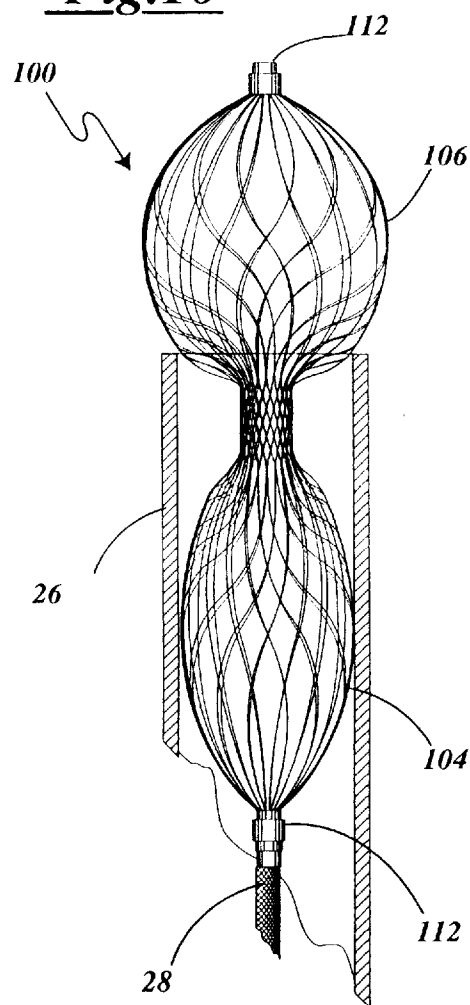
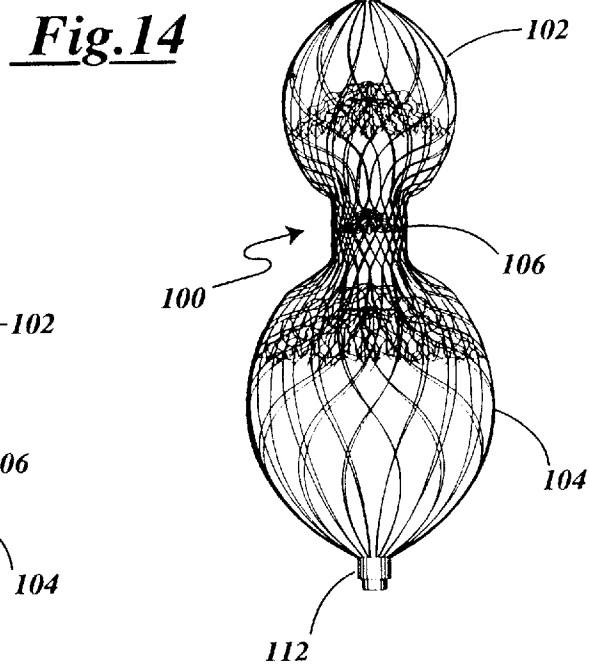
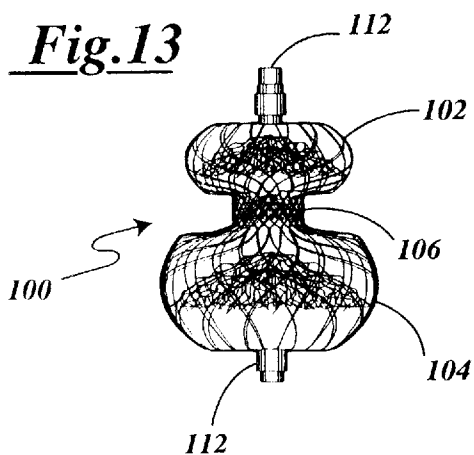
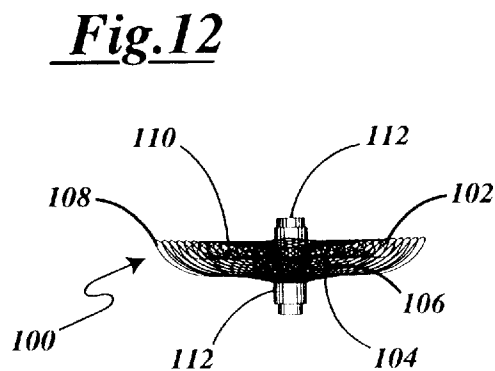
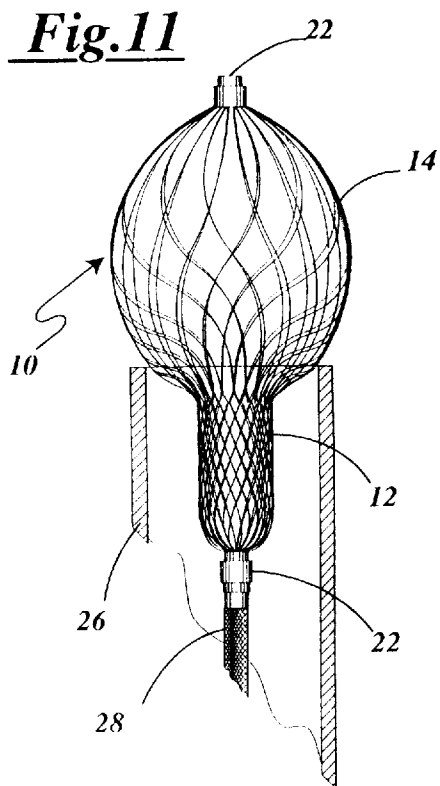


Fig.10





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Fig.15

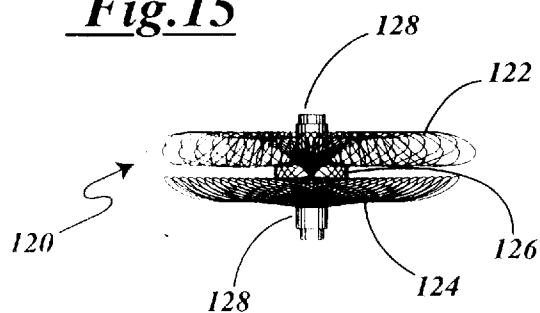


Fig.16

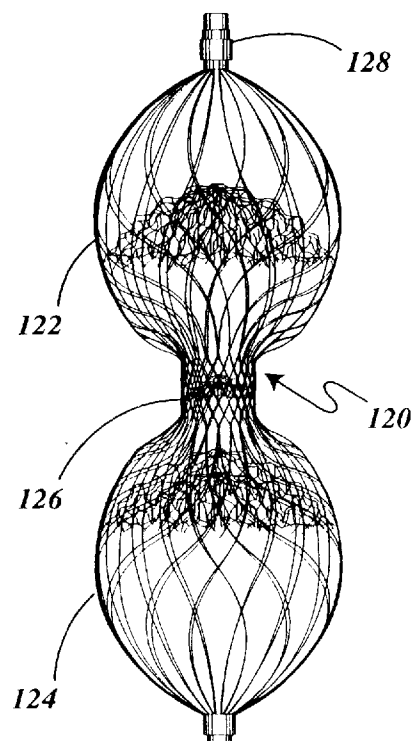


Fig.17

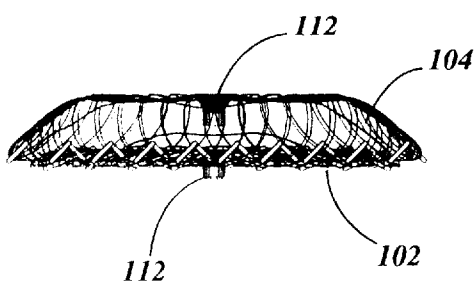


Fig.18

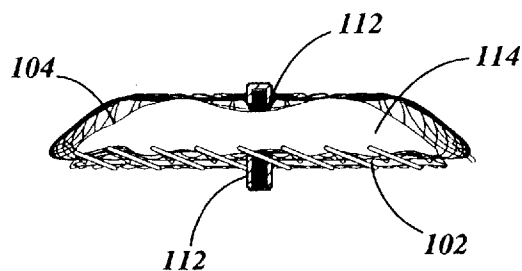


Fig.19

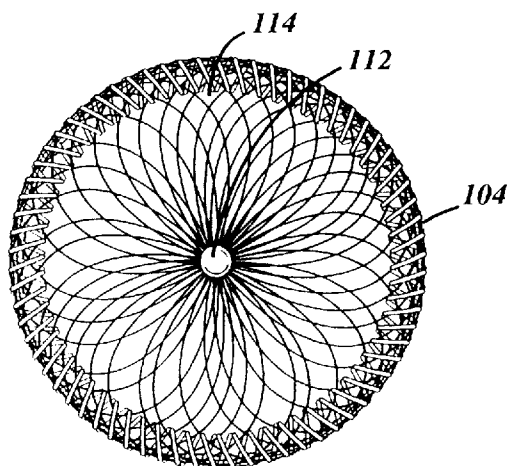


Fig.20

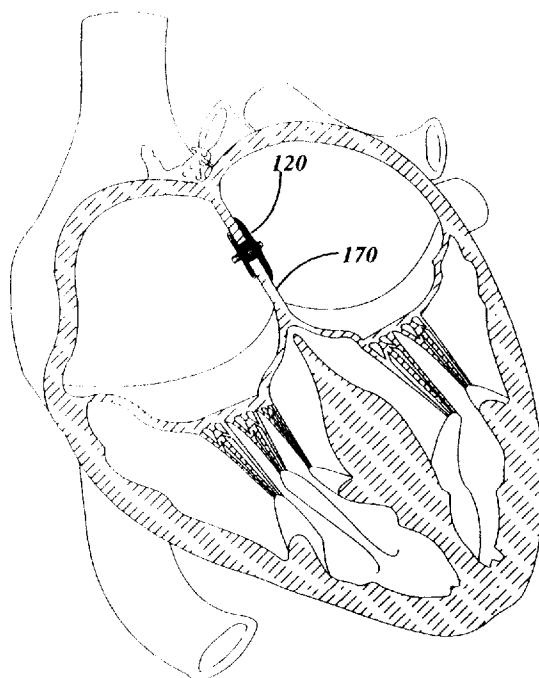
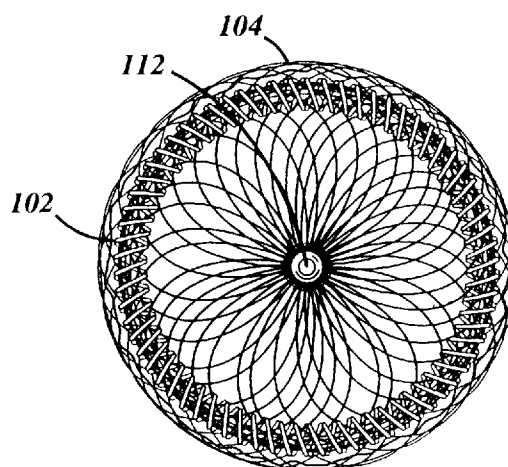


Fig.21

Fig.22

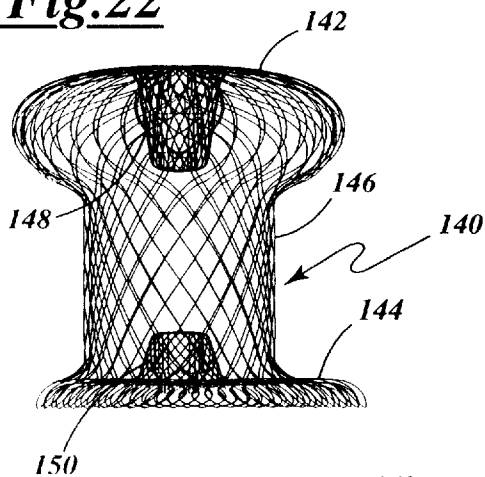


Fig.23

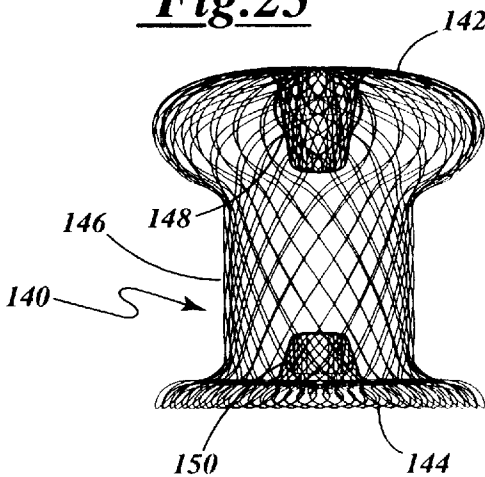


Fig.24

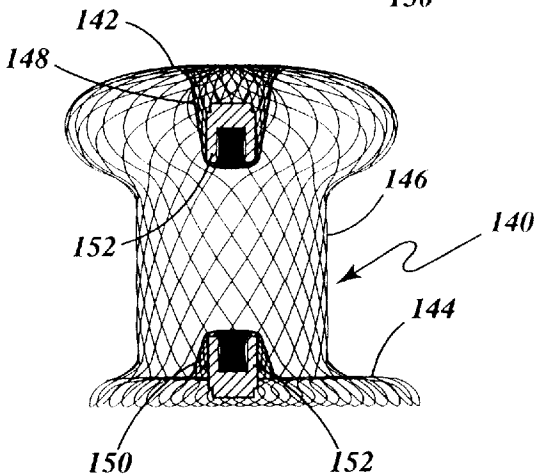


Fig.25

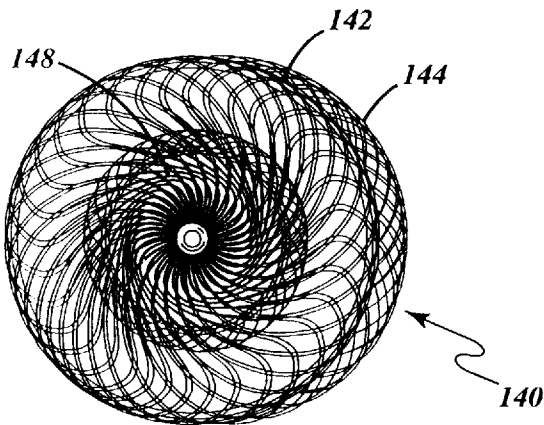


Fig.26

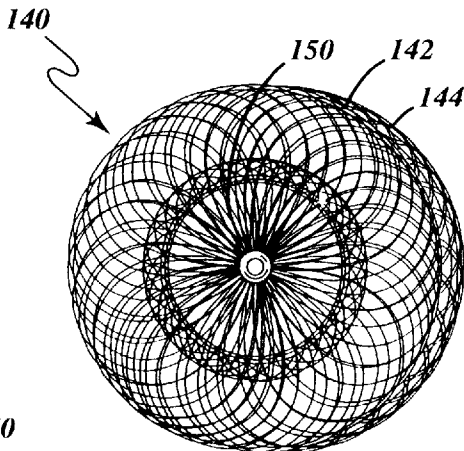


Fig.27

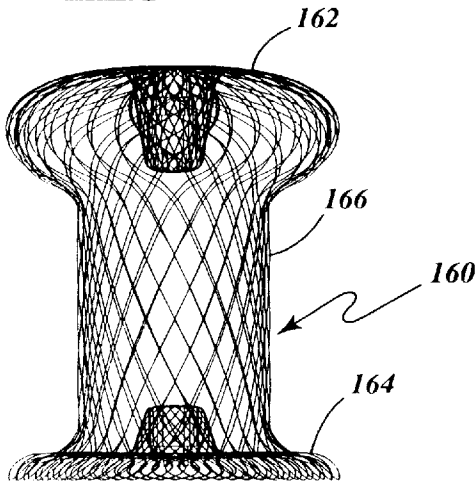


Fig.28

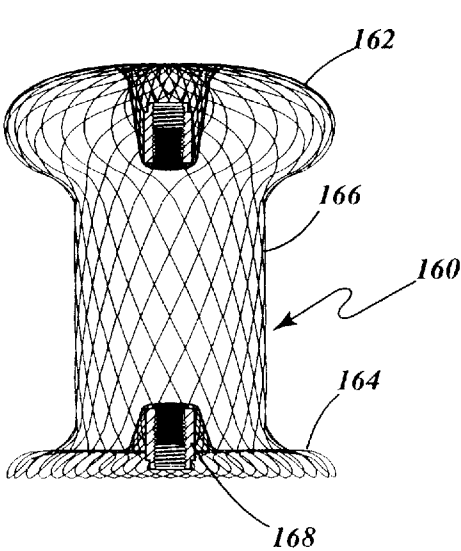


Fig.29

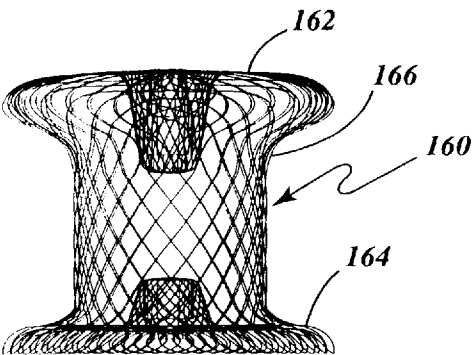


Fig.30

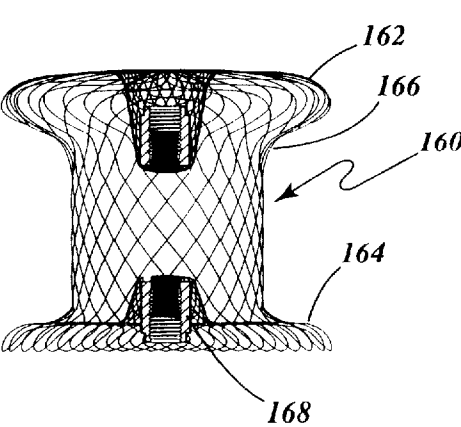


Fig.31

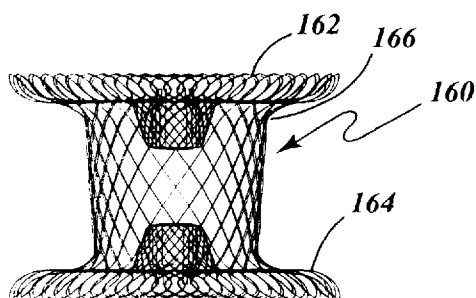
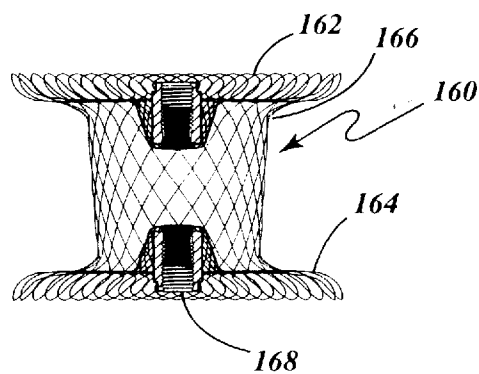


Fig.32



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**PERCUTANEOUS CATHETER DIRECTED  
OCCLUSION DEVICES**

The present application is a Continuation-In-Part of application Ser. No. 08/647,712 filed on May 14, 1996, now U.S. Pat. No. 5,725,552 and entitled PERCUTANEOUS CATHETER DIRECTED INTRAVASCULAR OCCLUSION DEVICE which is a Continuation-In-Part of co-pending application Ser. No. 08/272,335, filed on Jul. 8, 1994, still pending and entitled "METHOD OF FORMING MEDICAL DEVICES; INTRAVASCULAR OCCLUSION DEVICES".

**BACKGROUND OF THE INVENTION**

**I. Field of the Invention**

The present invention generally relates to intravascular devices for treating certain medical conditions and, more particularly, relates to a low profile intravascular occlusion devices for treating congenital defects including Atrial and Ventricular Septal Defects (ASD and VSD respectively) and Patent Ductus Arteriosus (PDA). The devices made in accordance with the invention are particularly well suited for delivery through a catheter or the like to a remote location in a patient's heart or in analogous vessels or organs within a patient's body.

**II. Description of the Related Art**

A wide variety of intra cardiac devices are used in various medical procedures. For example, certain intravascular devices, such as catheters and guide wires, are generally used simply to deliver fluids or other medical devices to specific locations within a patient's heart, such as a selective coronary artery within the vascular system. Other, frequently more complex, devices are used in treating specific conditions, such as devices used in removing vascular occlusions or for treating septal defects and the like.

In certain circumstances, it may be necessary to occlude a patient's vessel, such as to stop blood flow through an artery to a tumor or other lesion. Presently, this is commonly accomplished simply by inserting, for example, Ivalon particles (a trade name for vascular occlusion particles) and short sections of coil springs into a vessel at a desired location. These "embolization agents" will eventually become lodged in the vessel, frequently floating downstream of the site at which they are released before blocking the vessel. This procedure is often limited in its utility, in part, due to the inability to precisely position the embolization agents. These embolization agents are not commonly used as an intra cardiac occluding device.

Balloon catheters similar to that disclosed by Landymore et al. in U.S. Pat. No. 4,836,204 have been used by physicians to temporarily occlude a septal defect until the patient stabilizes enough for open heart surgical techniques. When using such a catheter, an expandable balloon is carried on a distal end of a catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place. If the balloon is not filled enough, it will not be firmly lodged in the septal defect and may rotate and loosen from the septal wall, thereby being released into the blood flowing from the right or left ventricular chamber. Overfilling the balloon is an equally undesirable occurrence which may lead to the rupture of the balloon and release of resins into the patient's bloodstream.

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Mechanical embolization devices, filters and traps have been proposed in the past, representative examples of which are disclosed in King et al., U.S. Pat. No. 3,874,388 (the '388 patent), Das, U.S. Pat. No. 5,334,217 (the '217 patent), Sideris, U.S. Pat. No. 4,917,089 (the '089 patent) and Marks, U.S. Pat. No. 5,108,420 (the '420 patent). The '388, '217, '089, and '420 devices are typically pre-loaded into an introducer or delivery catheter and are not commonly loaded by the physician during the medical procedure. During deployment of these devices, recapture into the delivery catheter is difficult if not impossible, thereby limiting the effectiveness of these devices.

Significantly, the size of these devices is inherently limited by the structure and form of the device. When using occluding devices such as the '089, '388, '217, or '420 plug to occlude a septal defect, the pressure and therefore the chance of dislodgment of the device increases with the size of the defect. Consequently, these devices must have a very large retention skirt positioned on each side of the defect. Oftentimes, the position of the septal defect dictates the size of the retention skirt. In a membranous type septal defect, it is difficult if not improbable to be able to effectively position the '388, '217, '089, or '420 device without at least partially closing off the aorta. Also, these disclosed devices tend to be rather expensive and time-consuming to manufacture. Hence, it is desirable to provide a low profile device that is recoverable and retractable into the delivery system without increasing the overall thickness of the device which may be made with a relatively small retention skirt that is positionable within a membranous type septal defect without closing off the aorta.

Also, the shape of the prior devices (for example squares, triangles, pentagons, hexagons and octagons) require a larger contact area, having corners which extend to the free wall of the atria. Each time the atria contracts (approximately 100,000 times per day), internal wires within the prior art devices are bent creating structural fatigue fractures in approximately 30 percent of all cases. Furthermore, the previous devices require a French 14-16 introducing catheter, making it impossible to treat children affected with congenital defects with these devices.

Accordingly, it would be advantageous to provide a reliable embolization device which is both easy to deploy through a 6-7 French catheter and which can be accurately placed in a vessel or organ. It would also be desirable to provide a low-profile recoverable device for deployment in an organ of a patient's body.

**SUMMARY OF THE INVENTION**

It is accordingly a principal object of the present invention to provide a reliable, low-profile, intra cardiac occlusion device which may be formed to treat, for example, Ventricular Septal Defects (VSD), Atrial Septal Defects (hereinafter ASD), and Patent Ductus Arteriosus (hereinafter PDA). When forming these intravascular devices from a resilient metal fabric a plurality of resilient strands are provided, with the wires being formed by braiding to create a resilient material. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the braided fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The braided fabric so treated

defines an expanded state of a medical device which can be deployed through a catheter into a channel in a patient's body.

Embodiments of the present invention provide specific shapes for medical devices which may be made in accordance with the present invention to address identified medical needs and procedures. The devices have an expanded low-profile configuration and may include recessed clamps that attach to an end of a delivery device or guide wire allowing recovery of the device after placement. In use, a guide catheter is positioned and advanced in a patient's body such that the distal end of the catheter is adjacent a desired treatment site for treating a physiological condition. A preselected medical device of the present invention having a predetermined shape is then collapsed and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon, due to its memory property it will tend to substantially return to its expanded state adjacent the treatment site. The guide wire or delivery catheter is then released from the clamp and removed.

In accordance with a first of these embodiments, a generally elongate medical device has a generally tubular middle portion and a pair of expanded diameter portions, with one expanded diameter portion positioned at either end of the middle portion. The width of the middle portion approximates the wall thickness of the organ to be occluded, for example, the thickness dimension of the septum. The center of at least one of the expanded diameter portions may be offset relative to the center of the middle portion, thereby allowing occlusion of a membranous type ventricular septal defect while providing a retention skirt of sufficient size to securely close the abnormal opening in the septum. Each braided end of the device is held together with a clamp. The clamps are recessed into the expanded diameter portion of the device, thereby reducing the overall length dimension of the device and creating a low profile occluder.

In another embodiment, the medical device is generally bell-shaped, having an elongate body, a tapered first end, and a larger second end. The second end has a fabric disc which will be oriented generally perpendicular to an axis of a channel when deployed therein. The clamps which hold together the braided ends are recessed towards the center of the "bell" providing a low-profile device having a reduced overall height dimension.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a medical device in accordance with the present invention;

FIG. 2 is a side view of the medical device of the type shown in FIG. 1;

FIG. 3 is a top view of the medical device of the type shown in FIG. 1;

FIG. 4 is a partial sectional side elevational view of a molding element suitable for forming the medical device shown in FIG. 1;

FIG. 5 is a partial sectional perspective view of a patient's heart showing the medical device of the type shown in FIG. 1 deployed in a central shunt of a patient's vascular system;

FIG. 6 is an enlarged, front elevational view of a medical device suitable for occluding a PDA;

FIG. 7 is a partial sectional side elevational view of the PDA device of FIG. 6;

FIG. 8 is a top plan view of the PDA device of FIG. 6;

FIG. 9 is a bottom plan view of the PDA device of FIG. 6;

FIG. 10 is an enlarged, partial sectional view of a medical device suitable for occluding an ASD, shown stretched and partially extending out from the lumen of a delivery catheter;

FIG. 11 is an enlarged, partial sectional view of a medical device suitable for occluding a PDA, shown stretched and partially extending out from the lumen of a delivery catheter;

FIG. 12 is an enlarged front elevational view of an ASD device of the type shown in FIG. 10, shown in its pre-shaped configuration;

FIG. 13 is a side elevational view of the ASD device of FIG. 12, shown slightly stretched and filled with polyester fibers;

FIG. 14 is a side elevational view of the ASD device of FIG. 12, shown stretched and filled with polyester fibers;

FIG. 15 is an enlarged front elevational view of an alternate ASD device, shown in its pre-shaped configuration;

FIG. 16 is a side elevational view of the ASD device of FIG. 15, shown stretched and filled with polyester fibers;

FIG. 17 is an enlarged front elevational view of another alternate ASD device, shown in its pre-shaped configuration;

FIG. 18 is partial sectional side elevational view of the ASD device of FIG. 17;

FIG. 19 is partial sectional top plan view of the ASD device of FIG. 17;

FIG. 20 is partial sectional bottom plan view of the ASD device of FIG. 17;

FIG. 21 is a partial sectional side elevational view of the ASD device of FIG. 17 shown positioned within an ASD of a patient's heart;

FIG. 22 is an enlarged, front elevational view of a medical device suitable for occluding a VSD shown in its pre-shaped configuration;

FIG. 23 is a side elevational view of the VSD device of FIG. 22;

FIG. 24 is a partial sectional front elevational view of the VSD device of FIG. 22;

FIG. 25 is a top plan view of the VSD device of FIG. 22;

FIG. 26 is a bottom plan view of the VSD device of FIG. 22;

FIG. 27 is an enlarged front elevational view of an alternate VSD device, shown in its pre-shaped configuration; and

FIG. 28 is a partial sectional side elevational view of the VSD device of FIG. 27.

FIG. 29 is an enlarged front elevational view of an alternate VSD device, shown in its pre-shaped configuration;

FIG. 30 is a partial sectional side elevational view of the VSD device of FIG. 29;

FIG. 31 is an enlarged front elevational view of an alternate VSD or PDA device, shown in its pre-shaped configuration; and

FIG. 32 is a partial sectional side elevational view of the VSD or PDA device of FIG. 31.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a percutaneous catheter directed occlusion device for use in occluding an abnormal opening in a patients' body, such as an Atrial Septal Defect (ASD), a ventricular septal defect (VSD), a Patent Ductus

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arteriosus (PDA), and the like. In forming a medical device via the method of the invention, a planar or tubular metal fabric is provided.

Both the planar and tubular fabrics are formed of a plurality of wire strands having a predetermined relative orientation between the strands. The tubular fabric has metal strands which define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This tubular fabric is known in the fabric industry as a tubular braid.

The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) as well as some other factors, such as the number of wires employed in a tubular braid, are important in determining a number of important properties of the device. For example, the greater the pick and pitch of the fabric, and hence the greater the density of the wire strands in the fabric, the stiffer the device will be. Having a greater wire density will also provide the device with a greater wire surface area, which will generally enhance the tendency of the device to occlude a blood vessel in which it is deployed. This thrombogenicity can be either enhanced by, e.g. a coating of a thrombolytic agent, or abated, e.g. by a coating of a lubricious, anti-thrombogenic compound. When using a tubular braid to form a device of the present invention, a tubular braid of about 4 mm in diameter with a pitch of about 50° and a pick of about 74 (per linear inch) would seem suitable for fabricating devices capable of occluding abnormal openings of about 2 mm to about 4 mm in inner diameter.

A metal planar fabric is a more conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like. In the woven fabric there is typically two sets of generally metal strands, with one set of strands being oriented at an angle, e.g. generally perpendicular (having a pick of about 90°), with respect to the other set. As noted above, the pitch and pick of the fabric (or, in the case of a knit fabric, the pick and the pattern of the knit, e.g. Jersey or double knits) may be selected to optimize the desired properties of the resulting medical device.

The wire strands of the planar or tubular metal fabric are preferably manufactured from so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

Without any limitation intended, suitable wire strand materials may be selected from a group consisting of a cobalt-based low thermal expansion alloy referred to in the field as ELGEOLOY, nickel-based high temperature high-strength "superalloys" commercially available from Haynes International under the trade name HASTELLOY, nickel-based heat treatable alloys sold under the name INCOLOY by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wire strands is that the wires retain a suitable amount of the deformation induced by a molding surface (as described below) when subjected to a predetermined heat treatment.

In the preferred embodiment, the wire strands are made from a shape memory alloy, NiTi (known as nitinol) which

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is an approximately stoichiometric alloy of nickel and titanium and may also include other minor amounts of other metals to achieve desired properties. Handling requirements and variations of NiTi alloy composition are known in the art, and therefore such alloys need not be discussed in detail here. U.S. Pat. No. 5,067,489 (Lind) and U.S. Pat. No. 4,991,602 (Amplatz et al.), the teachings of which are incorporated herein by reference, discuss the use of shape memory NiTi alloys in guide wires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic and are said to be "super elastic" or "pseudo elastic". This elasticity allows a device of the invention to return to a preset expanded configuration for deployment.

When forming a medical device in accordance with the present invention, an appropriately sized piece of tubular or planar metal fabric is inserted into a mold, whereby the fabric deforms to generally conform to the shape of the cavities within the mold. The shape of the cavities are such that the metal fabric deforms into substantially the shape of the desired medical device. The ends of the wire strands of the tubular or planar metal fabric should be secured to prevent the metal fabric from unraveling. A clamp or welding, as further described below, may be used to secure the ends of the wire strands.

In the case of a tubular braid, a molding element may be positioned within the lumen of the braid prior to insertion into the mold to thereby further define the molding surface. If the ends of the tubular metal fabric have already been fixed by a clamp or welding, the molding element may be inserted into the lumen by manually moving the wire strands of the fabric apart and inserting the molding element into the lumen of the tubular fabric. By using such a molding element, the dimensions and shape of the finished medical device can be fairly accurately controlled and ensures that the fabric conforms to the mold cavity.

The molding element may be formed of a material selected to allow the molding element to be destroyed or removed from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material. Once the material has been heat treated in contact with the mold cavities and molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The glass shards can then be removed from the enclosure of the metal fabric.

Alternatively, the molding element can be formed of a material that can be chemically dissolved, or otherwise broken down, by a chemical agent which will not substantially adversely affect the properties of the metal wire strands. For example, the molding element can be formed of a temperature resistant plastic resin which is capable of being dissolved with a suitable organic solvent. In this instance, the fabric and the molding element can be subjected to a heat treatment to substantially set the shape of the fabric in conformance with the mold cavity and molding element, whereupon the molding element and the metal fabric can be emersed in the solvent. Once the molding element is substantially dissolved, the metal fabric can be removed from the solvent.

Care should be taken to ensure that the materials selected to form the molding element is capable of withstanding the heat treatment without losing its shape, at least until the

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shape of the fabric has been set. For example, the molding element could be formed of a material having a melting point above the temperature necessary to set the shape of the wire strands, but below the melting point of the metal forming the strands. The molding element and metal fabric can then be heat treated to set the shape of the metal fabric, whereupon the temperature can be increased to substantially completely melt the molding element, thereby removing the molding element from within the metal fabric. Those skilled in the art will appreciate that the shapes of the mold cavities and the molding elements may be varied in order to produce the medical device having a preselected size and shape.

It should be understood that the specific shape of a particular molding element produces a specific shape and other molding elements having different shape configurations may be used as desired. If a more complex shape is desired, the molding element and mold may have additional parts including a camming arrangement, but if a simpler shape is being formed, the mold may have few parts. The number of parts in a given mold and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device to which the metal fabric will generally conform.

When the tubular braid for example is in its relaxed configuration, the wire strands forming the tubular braid will have a first predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis conforming to the shape of the mold. When the fabric is so deformed the relative orientation of the wire strands of the metal fabric will change. When the mold is assembled, the metal fabric will generally conform to the molding surface of the cavity. The medical device has a preset expanded configuration and a collapsed configuration which allows the device to be passed through a catheter or other similar delivery device. The expanded configuration is generally defined by the shape of the fabric when it is deformed to generally to conform to the molding surface of the mold.

Once the tubular or planar metal fabric is properly positioned within a preselected mold with the metal fabric generally conforming to the molding surface of the cavities therein, the fabric can be subjected to a heat treatment while it remains in contact with the molding surface. Heat treating the metal fabric substantially sets the shapes of the wire strands in a reoriented relative position when the fabric conforms to the molding surface. When the metal fabric is removed from the mold, the fabric maintains the shape of the molding surfaces of the mold cavities to thereby define a medical device having a desired shape. This heat treatment will depend in large part upon the material of which the wire strands of the metal fabric are formed, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface.

After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in a deformed state. If a molding element is used, this molding element can be removed as described above.

The time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire strands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the

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fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a super elastic or pseudo elastic phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal will tend to "set" the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

Suitable heat treatments of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils, for example, are used in a number of medical devices, such as in forming the coils commonly carried around distal links of guide wires. A wide body of knowledge exists for forming nitinol in such devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention. Briefly, though, it has been found that holding a nitinol fabric at about 500 degrees centigrade to about 550 degrees centigrade for a period of about 1 to 30 minutes, depending upon the softness or hardness of the device to be made will tend to set the fabric in its deformed state, i.e., wherein it conforms to the molding surface of the mold cavities. At lower temperatures, the heat treatment time will tend to be greater (e.g., about 1 hour at about 350 degrees centigrade) and at higher temperatures the time will tend to be shorter (e.g., about 30 seconds at about 900 degrees centigrade). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors which will be well known to those skilled in this field.

Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. In the present invention, this can be accomplished by, for example, connecting electrodes to each end of the metal fabric. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire mold to the desired heat treating temperature in order to heat the metal fabric to the desired temperature. The materials, molding elements and methods of molding a medical device from a tubular or planar metal fabric is further described in co-pending U.S. patent application Ser. No. 08/647,712, filed May 14, 1996 and assigned to the same assignee as the present invention, the entire disclosure of which is incorporated herein by reference.

Once a device having a preselected shape has been formed, the device may be used to treat a physiological condition of a patient. A medical device suitable for treating the condition, which may be substantially in accordance with one of the embodiments outlined below, is selected. Once the appropriate medical device is selected, a catheter or other suitable delivery device may be positioned within a channel in a patient's body to place the distal end of the delivery device adjacent the desired treatment site, such as immediately adjacent (or even within) the shunt of an abnormal opening in the patient's organ for example.

The delivery device (not shown) can take any suitable shape, but desirably comprises an elongate flexible metal shaft having a threaded distal end. The delivery device can be used to urge the medical device through the lumen of a catheter for deployment in a channel of a patient's body. When the device is deployed out the distal end of the catheter, the device will still be retained by the delivery device. Once the medical device is properly positioned within the shunt of the abnormal opening, the shaft of the delivery device can be rotated about its axis to unscrew the medical device from the delivery means.

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By keeping the medical device attached to the delivery means, the operator can retract the device for repositioning relative to the abnormal opening, if it is determined that the device is not properly positioned within the shunt. A threaded clamp attached to the medical device allows the operator to control the manner in which the medical device is deployed out the distal end of the catheter. When the device exits the catheter, it will tend to resiliently return to a preferred expanded shape which is set when the fabric is heat treated. When the device springs back into this shape, it may tend to act against the distal end of the catheter effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled by the operator to ensure proper positioning during deployment.

The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter. For example, An ASD occluding device may have a relatively elongated collapsed configuration wherein the devices are stretched along their axes (see FIG. 10). This collapsed configuration can be achieved simply by stretching the device generally along its axis, e.g. by manually grasping the clamps and pulling them apart, which will tend to collapse the expanded diameter portions of the device inwardly toward the device's axis. A PDA occlusion device also operates in much the same fashion and can be collapsed into its collapsed configuration for insertion into the catheter by applying tension generally along the axis of the device (see FIG. 11). In this regard, these devices are not unlike "Chinese handcuffs", which tend to constrict in diameter under axial tension.

If the device is to be used to permanently occlude a channel in the patient's body, one can simply retract the catheter and remove it from the patient's body. This will leave the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

Although the device will tend to resiliently return to its initial expanded configuration (i.e. its shape prior to being collapsed for passage through the catheter), it should be understood that it may not always return entirely to that shape. For example, it may be desirable that the device have a maximum outer diameter in its expanded configuration at least as large as and preferably larger than, the inner diameter of the lumen of the abnormal opening in which it is to be deployed. If such a device is deployed in a vessel or abnormal opening having a small lumen, engagement with the lumen will prevent the device from completely returning to its expanded configuration. Nonetheless, the device would be properly deployed because it would engage the inner wall of the lumen to seat the device therein.

When the device is deployed in a patient, thrombi will tend to collect on the surface of the wires. By having a

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greater wire density, the total surface area of the wires will be increased, increasing the thrombotic activity of the device and permitting it to relatively rapidly occlude the vessel in which it is deployed. It is believed that forming the occlusion device from a 4 mm diameter tubular braid having a pick of at least about 40 and a pitch of at least about 30° will provide sufficient surface area to substantially completely occlude an abnormal opening or blood vessel of 2 mm to about 4 mm in inner diameter in a suitable period of time. If it is desired to increase the rate at which the device occludes, any of a wide variety of known thrombotic agents can be applied to the device.

Referring now to the Figures, a discussion of the embodiments of the medical device of the present invention will next be presented. Referring first to FIGS. 1-3, there is shown generally a device 10 suitable for occluding a patent ductus arteriosus (PDA). PDA is essentially a condition wherein two blood vessels most commonly the aorta and the pulmonary artery adjacent the heart have a shunt between their lumens. Blood can flow directly between these two blood vessels through the shunt, compromising the normal flow of blood through the patient's vessels. The PDA device 10 has a generally bell-shaped body 12 and an outwardly extending forward end 14. The bell-shaped body 12 is adapted to be deployed within the shunt between the vessels while the forward end 14 is adapted to be positioned within the aorta to help seat the body of the device in the shunt. The sizes of the body 12 and the end 14 can be varied as desired for differently sized shunts. For example, the body 12 may have a diameter along its generally slender middle of about 10 mm and a length along its axis of about 25 mm. In such a device 10, the base of the body may flare generally radially outward until it reaches an outer diameter equal to that of the forward end 14 which may be on the order of about 20 mm in diameter.

The base 12 desirably flares out relatively rapidly to define a shoulder 16 tapering radially outwardly from the middle of the body 12. When the device 10 is deployed in a vessel, this shoulder 16 will abut the perimeter of the lumen being treated with higher pressure. The forward end 14 is retained within the vessel and urges the base of the body 12 open to ensure that the shoulder 16 engages the wall of the vessel to prevent the device from becoming dislodged from within the shunt.

A PDA occlusion device 10 of this embodiment of the invention can advantageously be made in accordance with the method outlined above, namely deforming a tubular metal fabric to generally conform to a molding surface of a mold and heat treating the fabric to substantially set the fabric in its deformed state. As noted above, the ends 18 and 20 of the tubular braid should be secured in order to prevent the braid from unraveling. In the preferred embodiment, clamps 22 are used to tie together the respective ends of the wire strands on each end 18 and 20 of the tubular braid. It is to be understood that other suitable fastening means may be attached to the ends in other ways, such as by welding, soldering, brazing, use of biocompatible cementitious material or in any other suitable fashion. Each clamp 22 may include a threading 24 that serves to connect the device 10 to a delivery system (not shown). In the embodiment shown, the clamp 22 is generally cylindrical in shape and has a crimping recess for receiving the ends of the wire strands to substantially prevent the wires from moving relative to one another.

When using untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of the

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braid cut to form the device are constrained relative to one another. The clamps 22 are useful to prevent the braid from unraveling at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps 22 hold the ends of the cut braid together and prevent the braid from unraveling. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder. When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual strands will tend to return to their heat set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more economical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device.

FIG. 4 shows a mold 30 generally comprising an upper and lower plate 32 and 34 respectively. Corresponding cavities 36 and 38 are formed within each plate 32 and 34 to thereby define the molding surface of each upper and lower plate. The cavity 36 of the upper plate 32 is adapted to form the body portion 12 of the PDA device 10, while the lower plate's cavity 38 is adapted to form the shoulder 16 and forward end 14 of the PDA device 10. The upper plate 32 includes an elongate generally tubular central segment 40 which is sized to form the elongate body 12 of the PDA device 10. A portion of the upper plate's cavity 36 optimally has an internal diameter slightly less than the natural, relaxed outer diameter of the tubular braid of which the device is formed. The compression of the braid helps yield devices with reproducibly sized bodies 12. The bottom plate 34 of the mold 30 has a generally disk shaped cavity 38 which desirably has a clamp port 42 approximately centered therein for receiving the clamp 22 attached to one end of the tubular metal fabric.

In use, the metal fabric is placed within the cylindrical portion 40 of the cavity 36 of the upper plate 32. The upper and lower plates 32 and 34 are then brought together such that the cavity 38 of the bottom plate 34 engages the fabric and tends to urge the fabric under compression generally radially outward. The fabric will then be enclosed generally within the cavities 36 and 38 of the plates and will generally conform to the inner surface of the cavities. If one prevents the entire clamp 22 from passing through the clamp port 42, the fabric will be spaced slightly away from the inner surface of the face, yielding a slight dome shape in the forward end of the device. Although the illustrated embodiment includes such a dome shaped forward end 16, it is to be understood that the shoulder and forward end 14 may be substantially flat which can be accomplished by allowing the clamp 22 to be received entirely within the clamp port 42 in the end plate.

Once the fabric is compressed, the fabric can be subjected to a heat treatment such as is outlined above. When the mold 30 is open again by moving the upper and lower plates 32 and 34 away from one another, the fabric will generally retain its deformed, compressed configuration. The formed device 10 can be collapsed, such as by urging the clamps 22 generally axially away from one another, which will tend to collapse the device 10 toward its axis. The collapsed device can then be attached to a delivery device 28 and passed through a catheter 26 for deployment in a preselected site in the patient's body.

FIG. 5 schematically illustrates a PDA device 10 positioned in a patient's heart to occlude a PDA. The device 10

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is shown positioned in a shunt, which extends between a patient's aorta "A" and the pulmonary artery "P". The device is passed through the PDA such as by keeping the device 10 collapsed within a catheter, and the shoulder 16 of the device can be allowed to elastically expand to substantially recover its thermally set, "remembered" shape from the heat treatment process, such as by urging the device distally to extend beyond the distal end of the catheter. The shoulder 16 should be larger than the lumen of the shunt of the PDA.

The device can then be retracted so that the shoulder 16 engages the wall of the pulmonary artery P. If one continues to retract the catheter, the engagement of the device 10 with the wall of the PDA will tend to naturally pull the body portion 12 of the device from the catheter, which will permit the body portion 12 to return to its expanded configuration. The body portion 12 should be sized so that it will frictionally engage the lumen of the PDA's shunt. The device will then be held in place by the combination of the friction between the body portion 12 and the lumen of the shunt and the aortic blood pressure against the shoulder 16 of the device. Over a relatively short period of time, thrombi will form in and on the device 10 and the thrombi will occlude the PDA. Those skilled in the art will appreciate that in order to speed up the occlusion of the device of the present invention, the device may be coated with a suitable thrombogenic agent, filled with a polyester fiber (see FIGS. 12-16), filled with a nylon sheet (see FIGS. 17-20) or braided with an increased number of wire strands.

Referring next to FIGS. 6-9, an alternative preferred PDA device 50 is shown. The device 50 includes a tapered cylindrical body portion 52 and a shoulder 54 extending radially outward from an end of the body portion. Each end 56 and 58 of the braided fabric is depressed inward towards the center of the lumen of the body portion 52. In this manner, clamps 60 attach to the ends of the tubular fabric are recessed within the device 50, thereby reducing the overall length of the PDA device and further creates a device lower in profile.

FIGS. 12-14 and 17-20 illustrates an alternate preferred embodiment of a medical device 100 in accordance with the present invention for correcting an atrial septal defect (ASD). With reference to FIGS. 12 and 17-20, the device 100 in its relaxed, unstretched state has two aligned disks 102 and 104 linked together by a short middle cylindrical section 106. It is proposed that this device 100 may also be well suited in occluding defects known in the art as patent foramen ovale (hereinafter PFO). Those skilled in the art will appreciate that a device of this configuration may also be suitable for use in a transcatheter closure during a Fenestrated Fontan's procedure. ASD is a congenital abnormality of the atrial septum characterized by structural deficiency of the atrial septum. A shunt may be present in the atrial septum, allowing flow between the right and left atriums. In large defects with significant left to right shunts through the defect, the right atrium and right ventricle are volume overloaded and the augmented volume is ejected into a low-resistance pulmonary vascular bed.

Pulmonary vascular occlusive disease and pulmonary atrial hypertension develops in adulthood. Patients with secundum ASD with a significant shunt (defined as a pulmonary blood flow to systemic blood flow ratio of greater than 1.5) are operated upon ideally at five years of age or whenever a diagnosis is made in later years. With the advent of two dimensional echocardiography and Doppler color flow mapping, the exact anatomy of the defect can be visualized. The size of the defect will correspond to the selected size of the ASD device 100 to be used.

The device **100**, shown in its unconfined or relaxed state in FIGS. **12** and **17–20**, is adapted to be deployed within the shunt comprising an ASD or a PFO (see FIG. **21**). For exemplary purposes, use of the device **100** in an ASD closure procedure will be described below. Turning first to the constructional features of the device **100**, the ASD occluder **100** is sized in proportion to the shunt to be occluded. In the relaxed orientation, the metal fabric is shaped such that two disk like members **102** and **104** are axially aligned and linked together by the short cylindrical segment **106**. The length of the cylindrical segment **106** preferably approximates the thickness of the atrial septum, and ranges between 2 to 20 mm. The proximal **102** and distal **104** disks preferably have an outer diameter sufficiently larger than the shunt to prevent dislodging of the device. The proximal disk **102** has a relatively flat configuration, whereas the distal disk **104** is cupped towards the proximal end slightly overlapping the proximal disk **102**. In this manner, the spring action of the device **100** will cause the perimeter edge **108** of the distal disk to fully engage the sidewall of the septum and likewise an outer edge of the proximal disk **102** will fully engage an opposite sidewall of the septum.

The ends of the tubular braided metal fabric device **100** are welded or clamped together with clamps **112**, similar to those described above to avoid fraying. Of course the ends may alternately be held together by other means readily known to those skilled in the art. The clamp **112** tying together the wire strands at one end also serves to connect the device to a delivery system (see FIG. **10**). In the embodiment shown, the clamp **112** is generally cylindrical in shape and has a recess for receiving the ends of the metal fabric to substantially prevent the wires comprising the woven fabric from moving relative to one another. The clamp **112** also has a threaded surface within the recess. The threaded recess is adapted to receive and engage a threaded distal end of a delivery device **28**.

The ASD occlusion device **100** of this embodiment of the invention can advantageously be made in accordance with the method outlined above. The device **100** is preferably made from a 0.005 inches nitinol wire mesh. The braiding of the wire mesh may be carried out with 28 picks per inch at a shield angle of about 64 degrees using a Maypole braider with 72 wire carriers. The stiffness of the ASD device **100** may be increased or decreased by altering the wire size, the shield angle, the pick size, the number of wire carriers or the heat treatment process. FIGS. **12–14** shows the interior lumen of the ASD device **100** filled with an occluding fiber of known suitable construction. FIGS. **17–20** shows the ASD device **100** having an occluding fabric **114** of known suitable construction contained within the interior of the device.

Those skilled in the art will recognize from the preceding discussion that the cavities of a mold must be shaped consistent with the desired shape of the ASD device. Also, it will be recognized that certain desired configurations may require that portions of the cavities be cammed. FIGS. **15** and **16** illustrates an alternate ASD device **120** shown slightly stretched and having a modified configuration. The proximal disk **122** is a mirror image of distal disk **124**, both of which are cup shaped. Each end is held by clamp **128**. The distance separating the proximal and distal disks **122** and **124** is preferably equal or slightly less than the length of the cylindrical segment **126**. The cup shape of each disk **122** and **124**, ensures complete contact between the outer edge of each disk **122** and **124** and the atrial septum. Upon proper placement, a new endocardium layer of endothelial forms

over the occlusion device **120**, thereby reducing the chance of bacterial endocarditis.

The distance separating the disks **122** and **124** of occluding device **120** may be increased to thereby provide an occluding device suitable for use in occluding a channel within a patient's body, having particular advantages in use as a vascular occlusion device. The device **120** of FIGS. **15** and **16** includes a generally tubular middle portion **126** and a pair of expanded diameter portions **122** and **124**. The expanded diameter portions are disposed at either end of the generally tubular middle portion. The relative sizes of the tubular middle section **126** and the expanded diameter portions **122–124** can be varied as desired. In this particular embodiment, the medical device is intended to be used as a vascular occlusion device to substantially stop the flow of blood through a patient's blood vessel. When the device **120** is deployed within a patient's blood vessel, it is positioned within the vessel such that its axis generally coincides with the axis of the vessel. The dumbbell shape is intended to limit the ability of the vascular occlusion device to turn at an angle with respect to the axis of the blood vessel to ensure that it remains in substantially the same position in which the operator deploys it within the vessel.

In order to relatively strongly engage the lumen of the blood vessel, the maximum diameter of the expanded diameter portions **122–124** should be selected so that it is at least as great as the diameter of the lumen of the vessel in which it is to be deployed and is optimally slightly greater than that diameter. When it is deployed within the patient's vessel, the vascular occlusion device will engage the lumen at two spaced apart locations. The device is desirably longer along its axis than the dimensions of its greatest diameter. This will substantially prevent the vascular occlusion device **120** from turning within the lumen at an angle to its axis, essentially preventing the device from becoming dislodged and tumbling along the vessel within the blood flowing through the vessel.

The relative sizes of the generally tubular middle portion **126** and expanded diameter portions **122–124** of the vascular occlusion device can be varied as desired for any particular application. For example, the outer diameter of the middle portion **126** may range between about  $\frac{1}{4}$  and about  $\frac{1}{3}$  of the maximum diameter of the expanded diameter portions and the length of the middle portion **126** may comprise about 20% to about 50% of the overall length of the device **120**. Although these dimensions are suitable if the device is to be used solely for occluding a vascular vessel, it is to be understood that these dimensions may be varied if the device is to be used in other applications, such as where the device is intended to be used simply as a vascular filter rather than to substantially occlude the entire vessel or where the device **120** is deployed to occlude an abnormal opening in an organ wall.

The aspect ratio (i.e., the ratio of the length of the device over its maximum diameter or width) of the device **120** illustrated in this embodiment is desirably at least about 1.0, with a range of about 1.0 to about 3.0 being preferred and then aspect ratio of about 2.0 being particularly preferred. Having a greater aspect ratio will tend to prevent the device **120** from rotating generally perpendicularly to its axis, which may be referred to as an end-over-end roll. So long as the outer diameter of the expanded diameter portions **122–124** of the device **120** is large enough to seat the device fairly securely against the lumen of the channel in which the device is deployed, the inability of the device to turn end-over-end will help keep the device deployed precisely where it is positioned within the patient's vascular system or

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in any other channel in the patient's body. Alternatively, having expanded diameter portions 122-124 which have natural relaxed diameters substantially larger than a lumen of the vessels in which the device is deployed should also suffice to wedge the device into place in the vessel without undue concern being placed on the aspect ratio of the device.

Turning now to FIGS. 22-26, a device 140 preferably suitable for occluding a membranous ventricular septal defect (VSD) is shown. The device 140 has an expanded preset configuration including two expanded diameter portions 142-144 and a reduced diameter portion 146 disposed between the two expanded diameter portions 142 and 144. Each of the expanded diameter portions 142 and 144 has a respective recess 148 and 150 extending inward from an outer surface of the expanded diameter portion 142 and 144. A clamp 152 attached to each end of the tubular metal fabric is contained within the corresponding recess 148-150 (see FIG. 24). The reduced diameter portion 146 has a length dimension which approximates a thickness of the abnormal opening formed in the septal wall. The expanded preset configuration of the device 140 is deformable to a lesser cross sectional dimension for delivery through a channel in a patient's body as described above. An inner surface of the expanded diameter portions may be concave or cupped (similar to that shown in FIGS. 15-16) to ensure that the outer perimeter of each diameter portion contacts the septal wall. Also, at least one of the expanded diameter portions 142 or 144 is offset relative to the reduced diameter portion 146. Thus, a center of one of the expanded diameter portion 142-144 will not align with the center of the reduced diameter portion 146. In this manner, when the abnormal opening is near the aorta, the offset retention skirt or expanded diameter portion 142-144 will not enclose the aorta upon placement.

FIGS. 27 and 28 illustrate another alternate preferred VSD device 160 wherein the center of the both expanded diameter portions 162-164 and the reduced diameter portion 166 are aligned. Clamps 168 are attached to the ends of the metal fabric and are recessed inward to provide a low profile occluding device. The clamps 168 may have internal or external threading for attachment to a delivery device or guidewire. A device 160 of this shape is preferably used in occluding a muscular type ventricular septal defect. The delivery of the VSD device is similar to that described above.

FIGS. 29 and 30 illustrate another embodiment of a device suitable for occluding a muscular VSD. The device of FIGS. 29 and 30 is similar to the VSD device shown in FIGS. 27 and 28 but includes modifications, wherein the length of the reduced diameter portion 166 is decreased and both expanded diameter portions 162-164 have been compressed thereby reducing the thickness dimension of each expanded diameter portion. FIGS. 31 and 32 illustrates another embodiment of a device similar to that shown in FIGS. 29 and 30. The device of FIGS. 31 and 32 is suitable for occluding a PDA, wherein the patient suffers from a pulmonary hyper tension. Both expanded diameter portions 162 and 164 are molded having a thin cross-section, to thereby avoid affecting the flow of fluid through the pulmonary vein or aorta. Further, the reduced diameter portion 166 is tapered to increase the surface area in contact with the tissue surrounding the defect.

Referring again to FIG. 21, the use of a device of the present invention will now be discussed in greater detail with respect to occluding a septal defect. The device 120, for example may be delivered and properly placed using two dimensional echocardiography and Doppler color flow map-

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ping. As indicated above, the delivery device 28 can take any suitable shape, preferably comprising an elongated flexible metal shaft similar to a conventional guide wire. The delivery device 28 is used to advance the ASD occlusion device 120 through the lumen of a small diameter cylindrical tube 26, such as a delivery catheter, for deployment. The ASD device 120 is loaded into the small diameter cylindrical tube 26 by stretching the same to put it in an elongated condition. The device may be inserted into the lumen of the tube 26 during the procedure or preassembled at a manufacturing facility, in that the devices of the present invention do not take on a permanent set when maintained in a compressed state.

From a femoral vein approach, the delivery catheter or tube 26 is passed across the ASD. The device 120 is advanced through the delivery catheter until the distal end becomes unconstrained on exiting the end of the catheter, whereupon it assumes its disk-like shape in the left atrium. The delivery catheter 26 is then pulled back in the proximal direction across the ASD and the delivery device 28 is likewise pulled in a proximal direction, urging the distal disk against the septum 170. The delivery catheter 26 is then further pulled away from the septum 170, allowing the proximal disk to extend out of the delivery catheter 26, where it resiliently returns to its predefined expanded disk-like shape. In this manner, the ASD device 120 is positioned such that the distal disk presses against one side of the septum 170 while the proximal disk presses against the other side of the septum 170. In order to increase its occluding ability, the device can contain polyester fibers (see FIGS. 13 and 14) or a nylon fabric (see FIGS. 17-20). In instances where the device is improperly deployed on a first try, the device 120 may be recovered by pulling the delivery device 28 proximally, thereby retracting the device 120 back into the delivery catheter 26 prior to a second attempt at positioning the device 120 relative to the defect.

When the ASD occluding device 120 is properly placed, the physician rotates the delivery device 28, unscrewing the delivery device 28 from the clamp 128 of the occluding device 120. The threads on the clamp 128 are such that the rotation of the delivery device 28 unscrews the delivery device from the clamp 128 of the occluding device 120, rather than merely rotating the occluding device 120. As noted above in alternate embodiments, the threaded clamp can enable the operator to maintain a hold on the device during deployment, or enables the operator to control the spring action during deployment of the device to ensure proper positioning.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use embodiments of the example as required. However, it is to be understood that the invention can be carried out by specifically different devices and that various modifications can be accomplished without departing from the scope of the invention itself.

What is claimed is:

1. A collapsible medical device, comprising a metal fabric having an expanded preset configuration and including a recess in each of a proximal end and a distal end of the preset configuration, said proximal and distal end each having means for securing each end attached to the metal fabric and contained within the recess, wherein said medical device is shaped to create an occlusion of an abnormal opening, whereby said expanded preset configuration is deformable to a lesser cross-sectional dimension for delivery through a

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channel in a patient's body, the woven metal fabric having a memory property such that the medical device tends to return to said expanded preset configuration when unconstrained.

2. The medical device as recited in claim 1, wherein the expanded preset configuration comprises two expanded diameter portions and a reduced diameter portion disposed between the two expanded diameter portions, said reduced diameter portion having a length dimension which approximates a thickness of the abnormal opening.

3. The medical device as recited in claim 2, wherein an inner surface of at least one of the expanded diameter portions is concave.

4. The medical device as recited in claim 2, wherein an inner surface of a first expanded diameter portions is concave and a length of the reduced diameter portion is dimensioned such that a perimeter edge of the first expanded diameter portion overlaps a perimeter edge of a second diameter portion.

5. The medical device as recited in claim 2, wherein a center of at least one of the expanded diameter portions is offset relative to the center of the reduced diameter portion.

6. The medical device as recited in claim 1, wherein the reduced diameter portion has a length approximating a thickness of a patient's atrial septum.

7. The medical device as recited in claim 1, wherein the reduced diameter portion has a length approximating a thickness of a patient's ventricular septum.

8. The medical device as recited in claim 1, wherein said expanded preset configuration is in a shape of a bell.

9. The medical device as recited in claim 1, wherein said expanded preset configuration is in a shape of a dumbbell.

10. A collapsible medical device, comprising a metal fabric having an expanded preset configuration in a shape of a bell and including a recess in each of a proximal end and a distal end, said proximal and distal end each having means for securing each end attached to the metal fabric and contained within the recess, wherein said medical device is shaped to create an occlusion in a patent ductus arteriosus, whereby said expanded preset configuration is deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the woven metal fabric having a memory property such that the medical device tends to return to said expanded preset configuration when unconstrained.

11. A collapsible medical device, comprising a metal fabric having an expanded preset configuration including two expanded diameter portions and a reduced diameter portion disposed between the two expanded diameter portions, each expanded diameter portion having a recess

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extending inward from an outer surface of the expanded diameter portion, such that means for securing an outer edge of said metal fabric is attached thereto and contained within each recess, said medical device is shaped to create an occlusion of an abnormal opening and said reduced diameter portion has a length dimension which approximates a thickness of the abnormal opening, whereby said expanded preset configuration is deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the woven metal fabric having a memory property such that the medical device tends to return to said expanded preset configuration when unconstrained.

12. The medical device as recited in claim 11, wherein the reduced diameter portion has a length approximating a thickness of a patient's atrial septum.

13. The medical device as recited in claim 11, wherein the reduced diameter portion has a length approximating a thickness of a patient's ventricular septum.

14. The medical device as recited in claim 11, wherein an inner surface of at least one of the expanded diameter portions is concave.

15. The medical device as recited in claim 11, wherein an inner surface of a first expanded diameter portions is concave and a length of the reduced diameter portion is dimensioned such that a perimeter edge of the first expanded diameter portion overlaps a perimeter edge of a second diameter portion.

16. The medical device as recited in claim 11, wherein a center of at least one of the expanded diameter portions is offset relative to the center of the reduced diameter portion.

17. The medical device as recited in claim 11, wherein said means for securing includes an internal threading for attachment to a delivery device.

18. A collapsible medical device, comprising a metal fabric having an expanded preset configuration and having a proximal end and a distal end of the preset configuration, said proximal and distal end each having means for securing each end attached to the metal fabric, wherein the expanded preset configuration comprises two expanded diameter portions and a reduced diameter portion disposed between the two expanded diameter portions, said reduced diameter portion having a tapered cross-section extending between the two expanded diameter portions, whereby said expanded preset configuration is deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the woven metal fabric having a memory property such that the medical device tends to return to said expanded preset configuration when unconstrained.

\* \* \* \* \*

**EXHIBIT A - Part 3**

US005944738A

**United States Patent** [19][11] **Patent Number:** **5,944,738****Amplatz et al.**[45] **Date of Patent:** **Aug. 31, 1999**[54] **PERCUTANEOUS CATHETER DIRECTED  
CONSTRICTING OCCLUSION DEVICE**

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[75] Inventors: **Kurt Amplatz**, St. Paul; **Michael R. Afremov**, St. Louis Park, both of Minn.

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[22] Filed: **Feb. 6, 1998**

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[51] **Int. Cl.<sup>6</sup>** ..... **A61B 17/08**[52] **U.S. Cl.** ..... **606/213**[58] **Field of Search** ..... 606/213, 151,  
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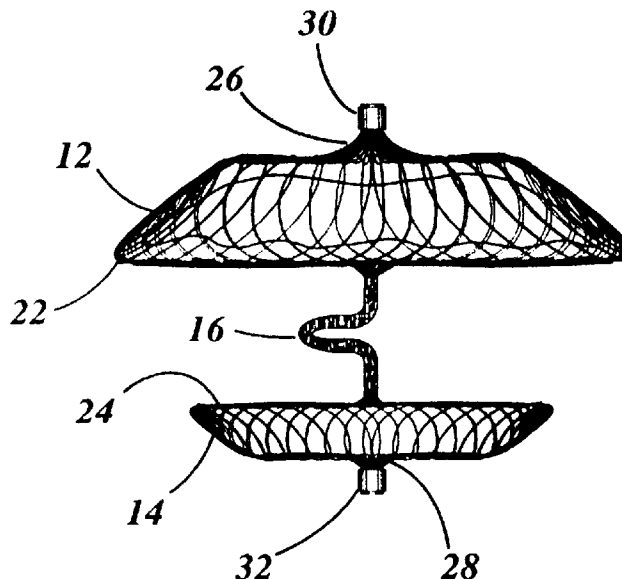
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[57]

**ABSTRACT**

A collapsible medical device and associated method for occluding an abnormal opening in, for example, a body organ, wherein the medical device is shaped from a shape memory metal fabric. The device may be used, for example, to non-surgically treat a patient having a Patent Foramen Ovale (PFO) and resulting paradoxical cerebral emboli. The device is preferably made from a continuous tubular metal fabric and includes two outer occluding portions and a resilient central, spring-like interconnecting member. The metal fabric may be heat treated within a mold in order to substantially set a desired shape of the device. The medical device includes a fastener for attaching to the end of a guide wire or delivery catheter. The medical device having the desired relaxed shape may be collapsed and delivered through a catheter or the like for deployment in a desired channel or opening in a patient's body.

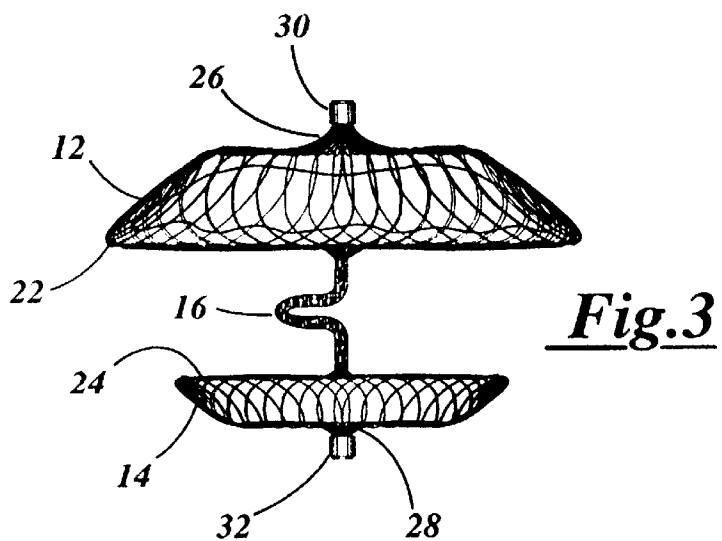
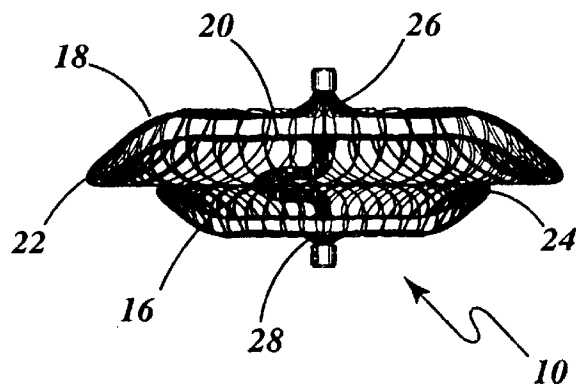
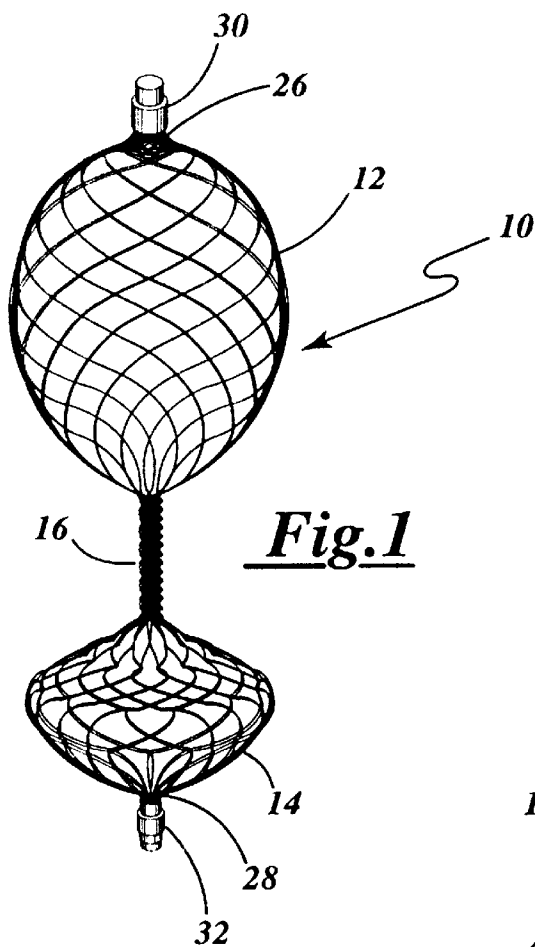
**30 Claims, 4 Drawing Sheets**

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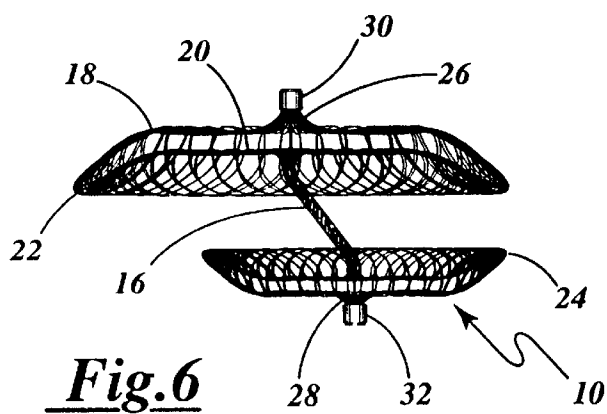
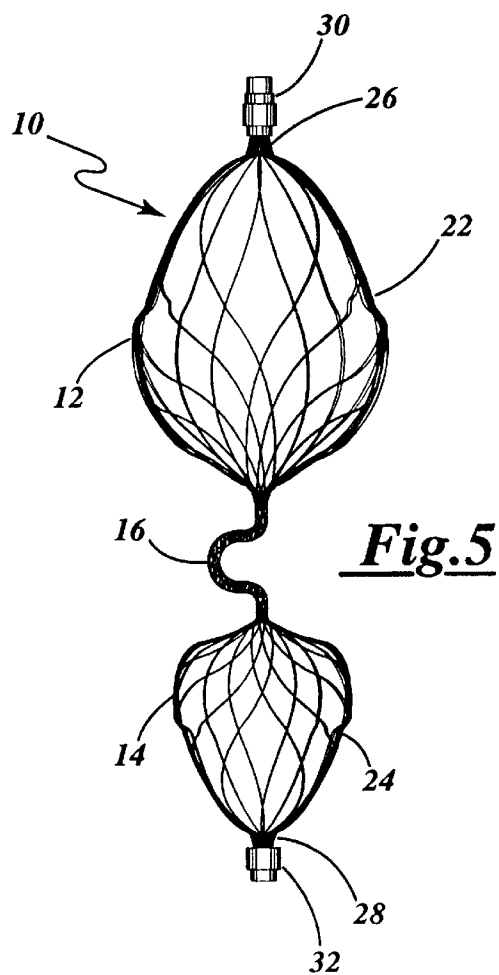
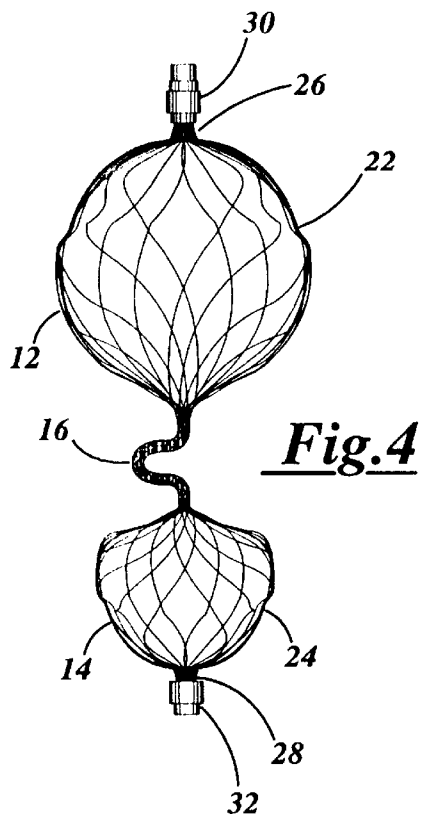


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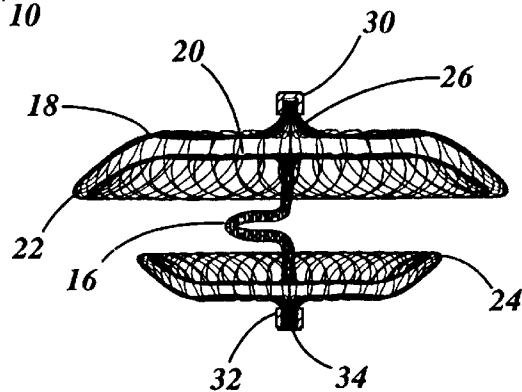
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**Fig. 7**



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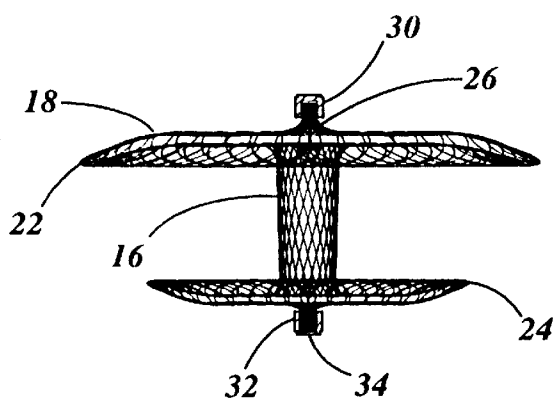


Fig. 8

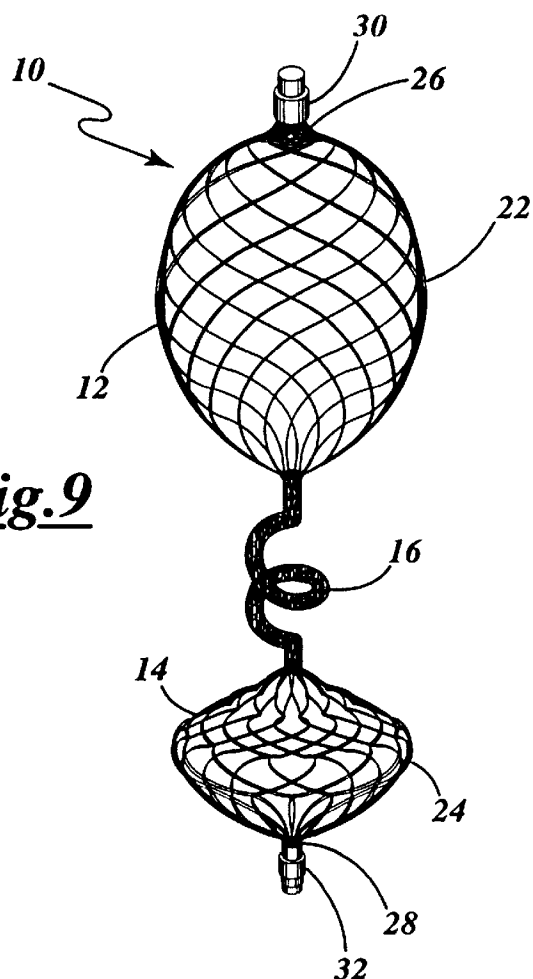


Fig. 9

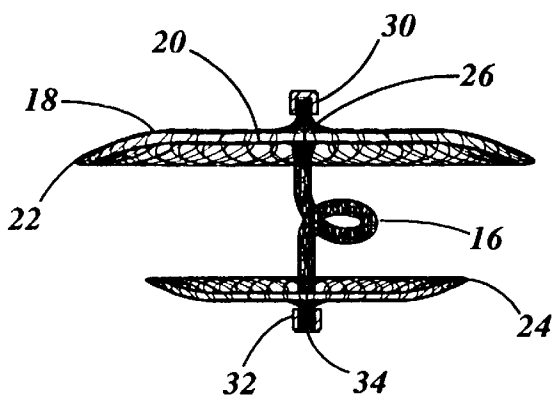


Fig. 10

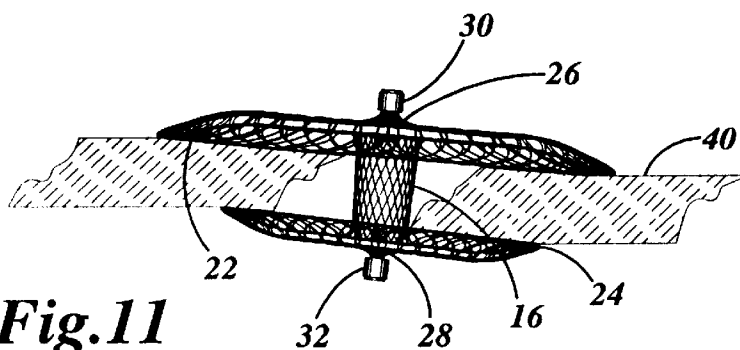


Fig. 11

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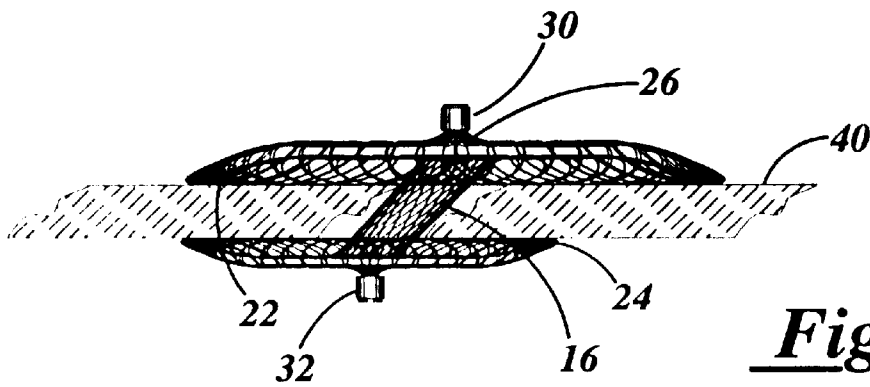


Fig. 12

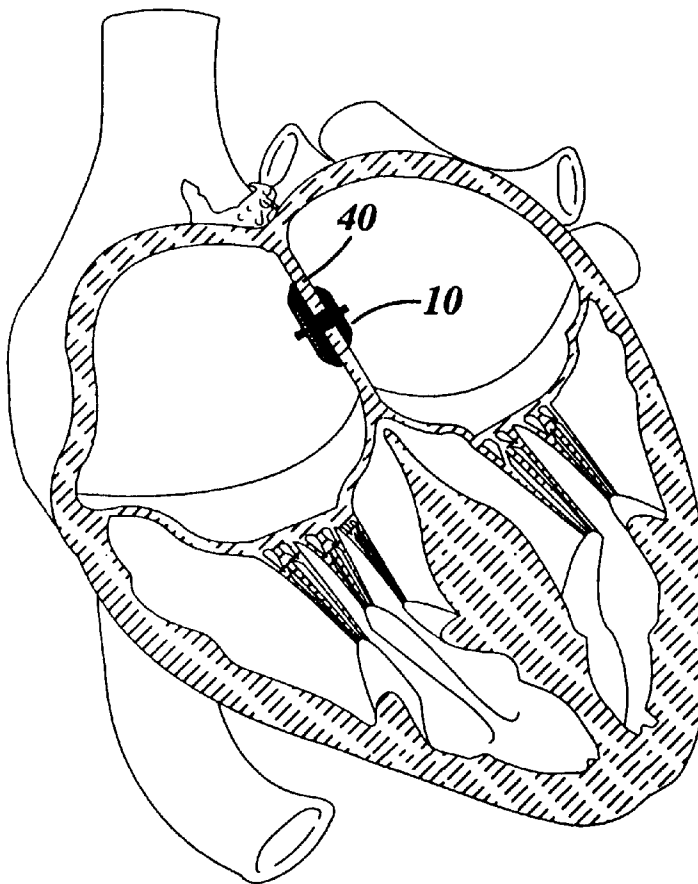


Fig. 13

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## PERCUTANEOUS CATHETER DIRECTED CONSTRICTING OCCLUSION DEVICE

### BACKGROUND OF THE INVENTION

#### I. Field of the Invention

The present invention relates generally to a device and non-surgical method for treating certain cardiac defects. More particularly, the present invention relates to a low profile occlusion device for non-surgical treatment of a patient having a Patent Foramen Ovale (PFO) and resulting paradoxical cerebral emboli. The device made in accordance with the invention is capable of automatically adjusting to a septal defect having eccentric openings and is particularly well suited for delivery through a catheter or the like to a remote location in a patient's heart or in analogous vessel or organ within a patient's body.

#### II. Description of the Related Art

A wide variety of intra cardiac devices are used in various medical procedures. Certain intravascular devices, such as catheters and guide wires, may be used to deliver fluids or other medical devices to a specific location within a patient's heart. For example, a catheter may be used to reach a selective coronary artery within the vascular system or the catheter and/or guidewire may be used to deliver a device to an interior chamber of the patient's heart. Complex devices may be delivered and used in treating specific abnormal conditions, such as devices used in removing vascular occlusions or devices used in treating septal defects and the like.

Balloon catheters and collapsible preformed polymeric devices similar to that disclosed by Landymore et al. in U.S. Pat. No. 4,836,204 and Linden et al. in U.S. Pat. No. 5,634,936 respectively have been used to occlude a septal defect. When using a balloon catheter similar to that disclosed in the '204 patent, an expandable balloon is carried on a distal end of the catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place. The '936 device is expanded and hardened by a ternary system that modifies the pH and hydrophilicity of the device (see '936 patent, col. 6, ln 40-45). If these devices are not expanded completely they may not firmly lodge in the septal defect and may rotate and loosen from the septal wall, thereby releasing into the blood stream. Overfilling the '204 device is an equally undesirable occurrence which may lead to the rupture of the balloon and release of resins into the patient's bloodstream.

Mechanical embolization devices have been proposed in the past for occluding defects in a patient's intravascular system. The devices typically include a pair of spaced apart patches each having an internal collapsible frame (similar to the frame and outer membrane of an umbrella), wherein the opposing patch and frame are interconnected by a conjoint member. The patches are typically aligned and attached to a common axis of the conjoint member. The conjoint member may be a rigid or semi-rigid hub which minimizes the movement of the patches both laterally and fore and aft to thereby firmly retain the patches against the septal wall adjacent the defect. Patches that are attached to a common axis of the hub may become problematic when the septal defect to be occluded has eccentric openings. Since the patches are attached to a common rigid axis, at least one of

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the eccentric openings may not be completely covered by the respective patch. The rigid or semi-rigid hub prevents adjustment of the patches to compensate for the eccentric openings.

Representative examples of such mechanical devices are disclosed in King et al., U.S. Pat. No. 3,874,388 (the '388 patent), Das, U.S. Pat. No. 5,334,217 (the '217 patent), European application No. 0541,063 A2 (the '063 application), Sideris, U.S. Pat. No. 4,917,089 (the '089 patent), and Marks, U.S. Pat. No. 5,108,420 (the '420 patent). These devices are typically pre-loaded into an introducer or delivery catheter prior to the implantation procedure and are not commonly loaded by the physician during the medical procedure. During deployment of these devices, recapture into the delivery catheter is difficult if not impossible, thereby limiting the effectiveness of these devices.

Prior to implantation of these devices, the thickness of the septal wall near the defect and the approximate width of the defect must be determined in order that an appropriately sized device may be provided. A balloon catheter and a calibrated guidewire having radiopaque regions of known length, may be utilized by a physician during a preliminary fluoroscopic procedure to estimate the defect's size, shape and thickness of the septal wall near the defect. Although useful, the defects exact size and shape cannot be determined, thereby increasing the possibility of leakage around the occluding device. Hence, a device that inherently adjusts to the shape and thickness of the defect would be desirable.

Significantly, the size of the prior devices is inherently limited by the structure and form of the device. Also, when using occluding devices such as those disclosed in the '089, '388, '217, or '420 patents to occlude a septal defect, the pressure and therefore the chance of dislodgment of the device increases with an increase in size of the defect. Consequently, the prior devices require an oversized retention skirt positioned on each side of the defect. Oftentimes, the position of the septal defect dictates the size of the retention skirt. In a membranous type septal defect, it is difficult if not improbable to be able to effectively position the '388, '217, '089, or '420 device without at least partially closing off the aorta. Also, these disclosed devices tend to be rather expensive and time-consuming to manufacture.

Further, the shape of the prior devices (for example squares, triangles, pentagons, hexagons and octagons) require a larger surface contact area and have corners which may extend to the free wall of the atria. Each time the atria contracts (approximately 100,000 times per day) the corners extending to the atria walls are bent, creating structural fatigue fractures in approximately 30 percent of all cases. Furthermore, the previous devices require a French 14-16 introducing catheter, making it impossible to treat children affected with congenital defects with these devices. Hence, it would be advantageous to provide a reliable embolization device which is both easy to deploy through a 6-7 French catheter and which automatically adjusts to the shape and thickness of the defect. The present invention addresses these and other disadvantages of the prior art.

### SUMMARY OF THE INVENTION

It is accordingly a principal object of the present invention to provide a reliable, low-profile, intra cardiac occlusion device capable of automatically adjusting the alignment within a septal defect having eccentric openings, wherein the device is suitable for treating septal defects including a

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Patent Foramen Ovale (PFO). PFO is essentially a condition wherein an abnormal, wide, opening is present in the septal wall between the two atria of the heart. Blood can flow directly between these two atria, compromising the normal flow of blood and efficiency of the patient's heart. The abnormal opening or septal defect may not extend perpendicularly through the septal wall. Rather, the center of the opening in the septal wall in the left atrium may be eccentric to the center of the opening in the septal wall in the right atrium, thereby requiring eccentric positioned "patches" to effectively occlude the defect. Also, the septal wall may be very thin requiring a minimal separation distance between the two occluding "patches". The device of the present invention is preferably formed from a continuous tubular metal fabric and includes two opposing spaced apart "discs", patches, or retention skirts interconnected by a flexible or resilient central member. The central member flexes both laterally and in the fore and aft directions while providing an inward tension against each of the discs.

When forming these intravascular devices from a resilient metal fabric a plurality of resilient strands or wires are provided, with the metal fabric being formed by braiding the resilient strands to create a resilient material. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the braided fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The braided fabric so treated defines a relaxed state of a medical device which can be stretched or expanded and deployed through a catheter into a channel in a patient's body. Those skilled in the art will appreciate that the cavities of the molds must mirror the desired shape of the device and further molding elements are described in co-pending application Ser. No. 08/647,712 filed on May 14, 1996, and entitled PERCUTANEOUS CATHETER DIRECTED INTRAVASCULAR OCCLUSION DEVICE which is assigned to the same assignee as the present invention, the entire disclosure of which is incorporated herein by reference.

The device of the present invention has a specific shape which is particularly well suited for occluding a PFO. The device has a relaxed low-profile configuration and includes clamps that allow attachment of the device to an end of a delivery device or guide wire (allowing recovery of the device after placement). In use, a guide catheter is positioned and advanced in a patient's body such that the distal end of the catheter is adjacent a desired treatment site for treating a physiological condition. The medical device of the present invention having a predetermined shape is then stretched and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon, due to its shape memory property it will tend to substantially return to its relaxed state adjacent the treatment site. The guide wire or delivery catheter is then released from the clamp and removed.

### OBJECTS

It is accordingly a principal object of the present invention to provide a device suitable for occluding a septal defect that is capable of automatically adjusting to eccentric openings of the septal defect while providing an inward tension on the occluding portions of the device.

Another object of the present invention is to provide a device suitable for occluding septal defects having eccentric

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openings, wherein the device is particularly well suited for delivery through a catheter or the like to a remote location in a patient's heart or in an analogous vessel or organ within a patient's body.

A further object of the present invention is to provide an occluding device having outer occluding portions and a flexible resilient central portion that pulls the outer occluding portions together.

These and other objects, as well as these and other features and advantages of the present invention will become readily apparent to those skilled in the art from a review of the following detailed description of the preferred embodiment in conjunction with the accompanying claims and drawings in which like numerals in the several views refer to corresponding parts.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a Patent Foramen Ovale occluding device in accordance with the present invention;

FIG. 2 is a side elevational view of the medical device of the type shown in FIG. 1;

FIG. 3 is a partial sectional side elevational view of the medical device of the type shown in FIG. 2, shown partially stretched along its longitudinal axis;

FIG. 4 is a side elevational view of the medical device of the type shown in FIG. 3, shown stretched along its longitudinal axis slightly more than in FIG. 3;

FIG. 5 is a side elevational view of the medical device of the type shown in FIG. 4, shown stretched along its longitudinal axis slightly more than in FIG. 4;

FIG. 6 is a side elevational view of the medical device of the type shown in FIG. 1 shown partially stretched, wherein the outer perimeter of the spaced apart discs are offset;

FIG. 7 is a partial sectional side elevational view of the medical device of the type shown in FIG. 1, shown partially stretched along its longitudinal axis;

FIG. 8 is a side elevational view of another embodiment of the present invention shown partially stretched along its longitudinal axis;

FIG. 9 is a side elevational view of another embodiment of the present invention shown partially stretched along its longitudinal axis;

FIG. 10 is a side elevational view of another embodiment of the present invention shown partially stretched along its longitudinal axis;

FIG. 11 is a partial sectional side elevational view of the embodiment of FIG. 8 shown occluding a PFO of the septal wall;

FIG. 12 is a partial sectional side elevational view of the embodiment of FIG. 8 shown occluding a PFO of the septal wall; and

FIG. 13 is a partial sectional side elevational view of the embodiment of FIG. 1 shown occluding an atrial septal defect.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a percutaneous catheter directed occlusion device for use in occluding an abnormal opening in a patient's body that is particularly well suited for occluding a PFO (see FIGS. 11-13). The occluding device includes two spaced apart occluding members interconnected by a flexible, resilient center portion. A clamp is attached to an outer end of each occluding member, wherein

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the clamps are adapted for coupling to the end of a guidewire or catheter for delivery to a pre-selected site within the patient. In the preferred embodiment, the occluding device is formed from a single continuous tubular metal fabric.

The tubular fabric is formed from a plurality of wire strands having a predetermined relative orientation between the strands. Those skilled in the art will appreciate that the pick and pitch of the braided wires may be varied depending upon the desired density of the fabric. The tubular fabric has metal strands which define two sets of essentially parallel generally spiraling and overlapping strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This tubular fabric is known in the fabric industry as a tubular braid.

The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) as well as some other factors, such as the number of wires employed in a tubular braid, the size or diameter of each wire in the braid, and the diameter of the braid are all important in determining a number of important properties of the device. For example, the greater the pick and pitch of the fabric, and hence the greater the density of the wire strands in the fabric, the stiffer the device will be. Also, the greater the diameter of each wire of the braid, the stiffer the device will be. Having a greater wire density will also provide the device with a greater wire surface area, which will generally enhance the tendency of the device to occlude the area in which it is deployed. This thrombogenicity can be either enhanced by a coating of a thrombolytic agent, or abated by a coating of a lubricious, anti-thrombogenic compound. When using a tubular braid to form a device of the present invention, a tubular braid of about 4 mm in diameter having approximately 72 braided wires is suitable for fabricating devices capable of occluding abnormal openings and/or septal defects.

The wire strands of the tubular metal fabric are preferably manufactured from so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

Without any limitation intended, suitable wire strand materials may be selected from a group consisting of a cobalt-based low thermal expansion alloy referred to in the field as ELGELOY, nickel-based high temperature high-strength "superalloys" (including nitinol) commercially available from, for example, Haynes International under the trade name HASTELLOY, nickel-based heat treatable alloys sold under the name INCOLOY by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wire strands is that the wires retain a suitable amount of the deformation induced by a molding surface (as described below) when subjected to a predetermined heat treatment.

In the preferred embodiment, the wire strands are made from a shape memory alloy, NiTi (known as nitinol) which is an approximately stoichiometric alloy of nickel and titanium and may also include other minor amounts of other metals to achieve desired properties. Handling requirements and variations of NiTi alloy composition are known in the art, and therefore such alloys need not be discussed in detail

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here. U.S. Pat. No. 5,067,489 (Lind) and 4,991,602 (Amplatz et al.), the teachings of which are incorporated herein by reference, discuss the use of shape memory NiTi alloys in guide wires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic and are said to be "super elastic" or "pseudo elastic". This elasticity allows a device of the invention to return to a preset configuration after deployment.

When forming a medical device in accordance with the present invention, an appropriately sized piece of tubular metal fabric is inserted into a mold, whereby the fabric deforms to generally conform to the shape of the cavities within the mold. The shape of the cavities are such that the metal fabric deforms into substantially the shape of the desired medical device. Cores within the cavities may be used to further form the shape of the fabric within the cavities. The ends of the wire strands of the tubular metal fabric should be secured to prevent the metal fabric from unraveling. A clamp or welding, as further described below, may be used to secure the ends of the wire strands.

During the molding procedure, a molding element may be positioned within the lumen of the tubular braid prior to insertion into the mold to thereby further define the molding surface. If the ends of the tubular metal fabric have already been fixed by a clamp or welding, the molding element may be inserted into the lumen by manually moving the wire strands of the fabric apart and inserting the molding element into the lumen of the tubular fabric. By using such a molding element, the dimensions and shape of the finished medical device can be fairly accurately controlled and ensures that the fabric conforms to the mold cavity.

The molding element may be formed of a material selected to allow the molding element to be destroyed or removed from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material. Once the material has been heat treated in contact with the mold cavities and molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The glass shards can then be removed from the enclosure of the metal fabric.

Alternatively, the molding element can be formed of a material that can be chemically dissolved, or otherwise broken down, by a chemical agent which will not substantially adversely affect the properties of the metal wire strands. For example, the molding element can be formed of a temperature resistant plastic resin which is capable of being dissolved with a suitable organic solvent. In this instance, the metal fabric and the molding element can be subjected to a heat treatment to substantially set the shape of the fabric in conformance with the mold cavity and molding element, whereupon the molding element and the metal fabric can be emersed in the solvent. Once the molding element is substantially dissolved, the metal fabric can be removed from the solvent.

Care should be taken to ensure that the materials selected to form the molding element are capable of withstanding the heat treatment without losing its shape, at least until the shape of the fabric has been set. For example, the molding element could be formed of a material having a melting point above the temperature necessary to set the shape of the wire strands, but below the melting point of the metal

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forming the strands. The molding element and metal fabric could then be heat treated to set the shape of the metal fabric, whereupon the temperature would be increased to substantially completely melt the molding element, thereby removing the molding element from within the metal fabric.

Those skilled in the art will appreciate that the specific shape of the molding element produces a specific shape of the molded device. If a more complex shape is desired, the molding element and mold may have additional parts including a camming arrangement, but if a simpler shape is being formed, the mold may have few parts. The number of parts in a given mold and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device to which the metal fabric will generally conform.

When the tubular braid, for example, is in its preformed relaxed configuration, the wire strands forming the tubular braid will have a first predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis conforming to the shape of the mold. When the fabric is so deformed the relative orientation of the wire strands of the metal fabric will change. When the mold is assembled, the metal fabric will generally conform to the molding surface of the interior cavity. After undergoing the shape memory process, the resulting medical device has a preset relaxed configuration and a collapsed or stretched configuration which allows the device to be passed through a catheter or other similar delivery device. The relaxed configuration is generally defined by the shape of the fabric when it is deformed to generally to conform to the molding surface of the mold.

Once the tubular or planar metal fabric is properly positioned within a preselected mold with the metal fabric generally conforming to the molding surface of the cavities therein, the fabric can be subjected to a heat treatment while it remains in contact with the molding surface. Suitable heat treatment processing of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils, for example, are used in a number of medical devices, such as in forming the coils commonly carried around distal links of guide wires. A wide body of knowledge exists for forming nitinol in such devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention. Briefly, though, it has been found that holding a nitinol fabric at about 500 degrees centigrade to about 550 degrees centigrade for a period of about 1 to 30 minutes, depending upon the softness or hardness of the device to be made will tend to set the fabric in its deformed state, i.e., wherein it conforms to the molding surface of the mold cavities. At lower temperatures, the heat treatment time will tend to be greater (e.g., about 1 hour at about 350 degrees centigrade) and at higher temperatures the time will tend to be shorter (e.g., about 30 seconds at about 900 degrees centigrade). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors known to those skilled in this field.

Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. In the present invention, this can be accomplished by, for example, connecting electrodes to each end of the metal fabric. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire mold to the desired heat treating temperature in

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order to heat the metal fabric to the desired temperature. The materials, molding elements and methods of molding a medical device from a tubular or planar metal fabric is further described in co-pending U.S. patent application Ser. No. 08/647,712, filed May 14, 1996 and assigned to the same assignee as the present invention, the entire disclosure of which is incorporated herein by reference.

Heat treating the metal fabric at temperatures ranging between 500–550 degrees centigrade substantially sets the shapes of the wire strands in a reoriented relative position conforming the shape of the fabric to the molding surface. When the metal fabric is removed from the mold, the fabric maintains the shape of the molding surfaces of the mold cavities to thereby define a medical device having a desired shape. After the heat treatment, the fabric is removed from contact with the molding cavity and will substantially retain its shape in a deformed state. If a molding element is used, this molding element can be removed as described above.

The time required for the heat treating process will depend in large part upon the material of which the wire strands of the metal fabric are formed and mass of the mold, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface. The required time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire strands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a super elastic or pseudo elastic phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal will tend to “set” the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

Once a device having a preselected shape has been formed, the device may be used to treat a physiological condition of a patient. A medical device suitable for treating the condition is selected. Once the appropriate medical device is selected, a catheter or other suitable delivery device may be positioned within a channel in a patient’s body to place the distal end of the delivery device adjacent the desired treatment site, such as immediately adjacent (or even within) the shunt of an abnormal opening in the patient’s organ for example.

The delivery device (not shown) can take any suitable shape, but desirably comprises an elongate flexible metal shaft having a threaded distal end. The delivery device can be used to urge the medical device through the lumen of a catheter for deployment in a channel of a patient’s body. When the device is deployed out the distal end of the catheter, the device will still be retained by the delivery device. Once the medical device is properly positioned within the shunt of the abnormal opening, the distal end of the catheter may be pressed against the medical device and the metal shaft or guidewire can be rotated about its axis to unscrew the medical device from the threaded distal end of the shaft. The catheter and guidewire are then withdrawn.

By keeping the medical device attached to the delivery means, the operator can retract the device for repositioning relative to the abnormal opening, if it is determined that the device is not properly positioned within the shunt. A

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threaded clamp attached to the medical device allows the operator to control the manner in which the medical device is deployed out the distal end of the catheter. When the device exits the catheter, it will tend to resiliently return to a preferred relaxed shape. When the device springs back into this shape, it may tend to act against the distal end of the catheter effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled by the operator to ensure proper positioning during deployment.

The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter. For example, the PFO occluding device may have a relatively elongated collapsed configuration wherein the device is stretched along its longitudinal axis (see FIG. 5). This collapsed configuration can be achieved simply by stretching the device generally along its axis, e.g. by manually grasping the clamps and pulling them apart, which will tend to collapse the relaxed diameter portions of the device inwardly toward the device's axis. Loading such a device into a catheter may be done at the time of implantation and does not require pre-loading of the introducer or catheter.

If the device is to be used to permanently occlude a channel in the patient's body, one can simply retract the catheter and remove it from the patient's body. This leaves the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

When the device is deployed in a patient, thrombi will tend to collect on the surface of the wires. By having a greater wire density, the total surface area of the wires will be increased, increasing the thrombotic activity of the device and permitting it to relatively rapidly occlude the vessel in which it is deployed. It is believed that forming the occlusion device from a 4 mm diameter tubular braid having a pick of at least about 40 and a pitch of at least about 30° will provide sufficient surface area to substantially completely occlude an abnormal opening in the septal wall. If it is desired to increase the rate at which the device occludes, any of a wide variety of known thrombotic agents can be applied to the device. Those skilled in the art will appreciate that an occluding membrane, fiber, or mesh may be positioned within either or both discs 12 and 14 to further enhance the occluding feature of each disc (see FIG. 3).

Having described the details of the invention, specific reference to the Figures will next be presented. The several Figures illustrate several embodiments of the invention wherein the central portion is resilient and pulls the outer discs towards each other. Referring first to the FIGS. 1 and 2, there is shown generally the device 10 suitable for occluding a Patent Foramen Ovale (PFO). In its relaxed, unstretched state (see FIG. 2), the device 10 generally includes two aligned discs 12 and 14 linked together by a

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resilient central portion 16. The plurality of braided wires form an outer 18 and inner 20 surface of each disc. The inner surface 20 of each disc may be concave or cupped (see also FIG. 7) to ensure that the outer perimeter edge 22 and 24 of each disc 12 and 14 respective contacts the septal wall 40.

When the device 10 is in a relaxed state, the discs 12 and 14 tend to overlap and the central portion 16 extends into the recess formed by the inner surface of the discs 12 and 14. In this manner, when the discs 12 and 14 are pulled apart (see FIG. 3) the spring-like action of the central portion 16 will cause the perimeter edge 22 and 24 of the corresponding disc to fully engage the sidewall of the septum (see FIGS. 11 and 12). FIGS. 3-5 illustrates sequentially the stretching, spring-like action of the bent central portion 16. Without any limitation intended, during the formation of the device 10, the tubular braid (in the region forming the central portion 16) is partially flattened to enhance the spring-like action of the central portion 16. FIG. 6 illustrates that the discs 12 and 14 may be offset laterally by stretching the central portion 16.

The ends 26 and 28 of the tubular braided metal fabric device 10 are welded or clamped together with corresponding clamps 30 and 32 to avoid fraying. Of course the ends may alternately be held together by other means readily known to those skilled in the art. Further, it is to be understood that other suitable fastening means may be attached to the ends 26 and 28 in other ways, such as by welding, soldering, brazing, use of biocompatible cementitious material or in any other suitable fashion. The clamps 30 and 32 tying together the wire strands at corresponding ends 26 and 28 also serve to connect the device to a delivery system. In the embodiment shown, the clamps 30 and 32 are generally cylindrical in shape and have a threaded bore 34 (see FIG. 7) for receiving the ends 26 and 28 of the metal fabric to substantially prevent the wires from moving relative to one another. The threaded bore 34 is adapted to receive and engage a threaded distal end of a delivery device.

FIGS. 8-10 show additional embodiments of the device 10 wherein the shape of the resilient central portion 16 is varied. The central portion 16 is flexible in both the lateral and fore and aft directions. This flexibility provides a self centering feature of the device, wherein the discs 12 and 14 tend to automatically center themselves around the adjacent opening of the defect (see FIGS. 11 and 12) while tending to pull the discs toward the other. The central portion 16 may include a helical spring-like shape (see FIG. 9), a coil shape (see FIG. 10), or a bent shape (see FIG. 2).

Those skilled in the art will appreciate that the device 10 is sized in proportion to the shunt to be occluded. The diameter of each disc 12 and 14 may be varied as desired for differently sized openings in the septal wall. Further, the length of the resilient central portion may be varied depending upon the thickness of the septal wall, and may range between 4 to 40 mm.

The PFO occlusion device 10 can advantageously be made in accordance with the method outlined above. The device is preferably made from a 0.005 inch nitinol wire mesh. The braiding of the wire mesh may be carried out with 28 picks per inch at a shield angle of about 64 degrees using a Maypole braider with 72 wire carriers. The stiffness of the PFO device 10 may be increased or decreased by altering the wire size, the shield angle, the pick size, braid diameter, the number of wire carriers, or the heat treatment process. Those skilled in the art will recognize from the preceding discussion that the cavities of a mold must be shaped consistent with the desired shape of the PFO device.

When using untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of the braid are constrained relative to one another. The clamps **30** and **32** are useful to prevent the braid from unraveling at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps **30** and **32** hold the ends of the cut braid together and prevent the braid from unraveling. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends may be welded together, such as by spot welding with a laser welder. When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual strands will tend to return to their heat set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more economical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device.

Use of a device **10** of the present invention will now be discussed in greater detail with respect to occluding a PFO. The device may be delivered and properly placed using two dimensional echocardiography and Doppler color flow mapping. As indicated above, the delivery device can take any suitable shape, preferably comprising an elongated flexible metal shaft similar to a conventional guide wire. The delivery device is used to advance the PFO occlusion device through the lumen of a small diameter cylindrical tube, such as a delivery catheter, for deployment. The PFO device **10** is loaded into the small diameter cylindrical tube by using a loading sheath to stretch the device and put the same in an elongated or stretched condition. The device may be inserted into the lumen of the tube during the procedure or preassembled at a manufacturing facility, in that the devices of the present invention do not take on a permanent set when maintained in a compressed state.

From a femoral vein approach, the delivery catheter or tube is passed across the PFO. The device **10** is advanced through the delivery catheter until the distal end becomes unconstrained on exiting the end of the catheter, whereupon it assumes its disc-like shape in the left atrium (see FIG. **13**). The delivery catheter is then pulled back in the proximal direction across the PFO and the delivery device is likewise pulled in a proximal direction, urging the distal disc against the septum. The delivery catheter is then further pulled away from the septum, allowing the proximal disc to extend out of the delivery catheter, where it resiliently returns to its predefined relaxed disc-like shape. In this manner, the PFO device is positioned such that the distal disc presses against one side of the septum while the proximal disc presses against the other side of the septum. In order to increase its occluding ability, the device can contain polyester fibers or a nylon fabric (see FIG. **3**). In instances where the device is improperly deployed on a first try, the device may be recovered by pulling the delivery device proximally, thereby retracting the device **10** back into the delivery catheter prior to a second attempt at positioning the device relative to the defect.

When the PFO occluding device is properly placed, the physician rotates the guidewire, unscrewing the threaded distal end of the guidewire from the clamp **30** or **32** of the occluding device **10**. The threads on the clamp are such that the rotation of the guidewire unscrews the guidewire from the clamp of the occluding device **10**, rather than merely

rotating the occluding device. As noted above, the threaded clamp can also enable the operator to maintain a hold on the device during deployment, or enables the operator to control the spring action during deployment of the device to ensure proper positioning.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use embodiments of the example as required. However, it is to be understood that the invention can be carried out by specifically different devices and that various modifications can be accomplished without departing from the scope of the invention itself.

What is claimed is:

1. A collapsible medical device, comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end, each end having means for securing the metal fabric attached thereto, thereby inhibiting unraveling of the metal fabric, said metal fabric having a relaxed configuration having two enlarged diameter portions and a central portion disposed between the two enlarged diameter portions wherein said central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device further having a collapsed configuration for delivery through a channel in a patient's body.

2. The device as recited in claim **1**, wherein each enlarged diameter portion has an inner and outer wall such that the inner wall of at least one of the enlarged diameter portions is at least partially concave.

3. The device as recited in claim **1**, wherein said central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

4. The device as recited in claim **1**, wherein said central portion is helically shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

5. The device as recited in claim **1**, wherein said central portion is coiled to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

6. The device as recited in claim **1**, wherein said central portion is bent to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

7. The device as recited in claim **2**, wherein said central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

8. The device as recited in claim **1**, wherein a separation distance between the two enlarged diameter portions is less than a thickness of a patient's atrial septum.

9. The medical device as recited in claim **1**, wherein an inner surface of a first enlarged diameter portion is at least partially concave and a length of the central portion is dimensioned such that a perimeter edge of the first enlarged diameter portion overlaps a perimeter edge of a second enlarged diameter portion.

10. The medical device as recited in claim **1**, said two enlarged diameter portions consisting of a first enlarged partially concave diameter portion and a second enlarged partially concave diameter portion.

11. The medical device as recited in claim **1**, said two enlarged diameter portions consisting of a first enlarged diameter portion and a second enlarged diameter portion, wherein the central portion may be flexed such that a first central axis of the first enlarged diameter portion is offset from a second central axis of the second enlarged diameter portion.

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12. The medical device as recited in claim 1, wherein said means for securing includes means for attachment to a delivery device.

13. A collapsible medical device, comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end, each end having means for securing the metal fabric attached thereto, thereby inhibiting unraveling of the metal fabric, said metal fabric having a relaxed configuration having two enlarged diameter portions and a resilient portion disposed between the two enlarged diameter portions wherein said resilient portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device further having a collapsed configuration for delivery through a channel in a patient's body.

14. The device as recited in claim 13, wherein each enlarged diameter portion has an inner and outer wall such that the inner wall of at least one of the enlarged diameter portions is at least partially concave.

15. The device as recited in claim 13, wherein said resilient portion is shaped to thereby pull the two enlarged diameter portions toward the other.

16. The device as recited in claim 13, wherein said resilient portion is helically shaped to thereby pull the two enlarged diameter portions toward the other.

17. The device as recited in claim 13, wherein said resilient portion is coiled to thereby pull the two enlarged diameter portions toward the other.

18. The device as recited in claim 13, wherein said resilient portion is bent to thereby pull the two enlarged diameter portions toward the other.

19. The medical device as recited in claim 13, said two enlarged diameter portions consisting of a first enlarged diameter portion and a second enlarged diameter portion, wherein the resilient portion may be flexed such that a first central axis of the first enlarged diameter portion is offset from a second central axis of the second enlarged diameter portion.

20. A collapsible medical device, comprising two enlarged diameter portions and a flexible central portion interconnecting the two enlarged diameter portions wherein said flexible central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device having a proximal end and a distal end, wherein at least one of the proximal and distal end includes means for securing said device to a delivery system, said device having a collapsed configuration for delivery through a channel in a patient's body.

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21. The device as recited in claim 20, wherein said device is formed from a metal fabric consisting of a plurality of woven metal strands.

22. The device as recited in claim 20, wherein each enlarged diameter portion has an inner and outer wall such that the inner wall of at least one of the enlarged diameter portions is at least partially concave.

23. The device as recited in claim 20, wherein said flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

24. The device as recited in claim 21, wherein said flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

25. The device as recited in claim 20, wherein a separation distance between the two enlarged diameter portions is less than a thickness of a patient's atrial septum.

26. The medical device as recited in claim 20, wherein an inner surface of a first enlarged diameter portion is at least partially concave and a length of the flexible central portion is dimensioned such that a perimeter edge of the first enlarged diameter portion overlaps a perimeter edge of a second enlarged diameter portion.

27. The medical device as recited in claim 20, wherein said means for securing includes means for attachment to a delivery device.

28. The medical device as recited in claim 1, wherein the flexible central portion is shaped to form a stretchable portion, and further wherein the flexible central portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in the relaxed configuration.

29. The medical device as recited in claim 13, wherein the resilient portion is shaped to form a stretchable portion, and further wherein the resilient portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in the relaxed configuration.

30. The medical device as recited in claim 20, wherein the flexible central portion is shaped to form a stretchable portion, wherein the flexible central portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in a preset configuration.

\* \* \* \* \*

**EXHIBIT A - Part 4**

US006123715A

**United States Patent** [19][11] **Patent Number:** **6,123,715****Amplatz**[45] **Date of Patent:** **Sep. 26, 2000**[54] **METHOD OF FORMING MEDICAL DEVICES; INTRAVASCULAR OCCLUSION DEVICES**[76] Inventor: **Curtis Amplatz**, 546 N. Lexington Pkwy., St. Paul, Minn. 55104

[ \* ] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

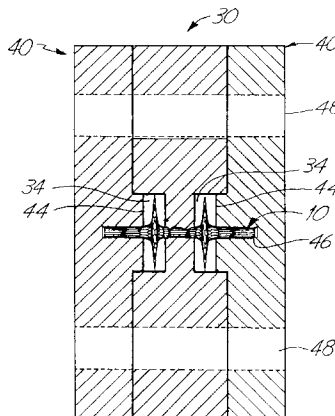
[21] Appl. No.: **08/272,335**[22] Filed: **Jul. 8, 1994**[51] Int. Cl.<sup>7</sup> ..... **A61M 29/00**[52] U.S. Cl. .... **606/200; 606/151; 623/11; 623/901**

[58] Field of Search ..... 606/1, 157, 213, 606/190-198, 200; 603/1, 11, 12, 901; 72/54; 29/527.1, DIG. 29

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Primary Examiner—Glenn K. Dawson  
 Attorney, Agent, or Firm—Fredrikson & Byron, P.A.

[57]

## ABSTRACT

The present invention provides a method of forming a medical device and medical devices which can be formed in accordance with the method. In one embodiment, the method includes the steps of a) providing a metal fabric formed of a plurality of strands formed of a metal which can be heat treated to substantially set a desired shape; b) deforming the metal fabric to generally conform to a surface of a molding element; c) heat treating the metal fabric in contact with the surface of the molding element to substantially set the shape of the fabric in its deformed state; and d) removing the metal fabric from contact with the molding element. The resulting metal fabric will define a medical device which can be collapsed for passage through a catheter or the like for deployment in a channel of a patient's body. Medical devices made in accordance with this method can have varying structures.

17 Claims, 11 Drawing Sheets

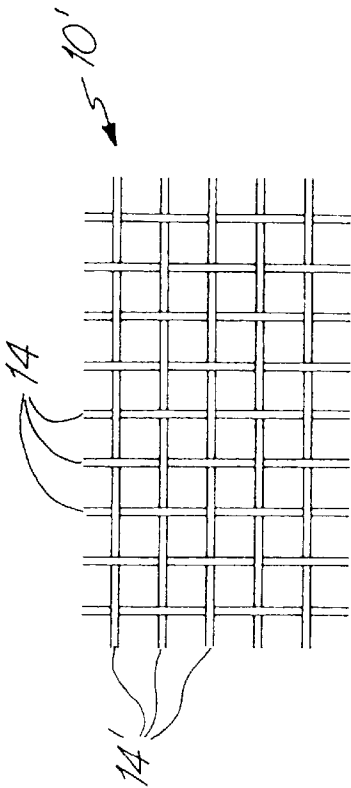


Fig. 1B

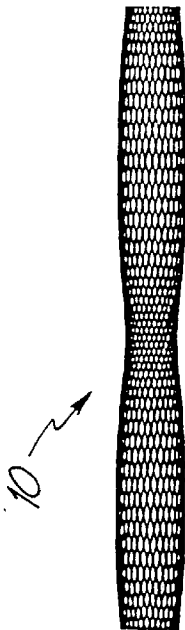


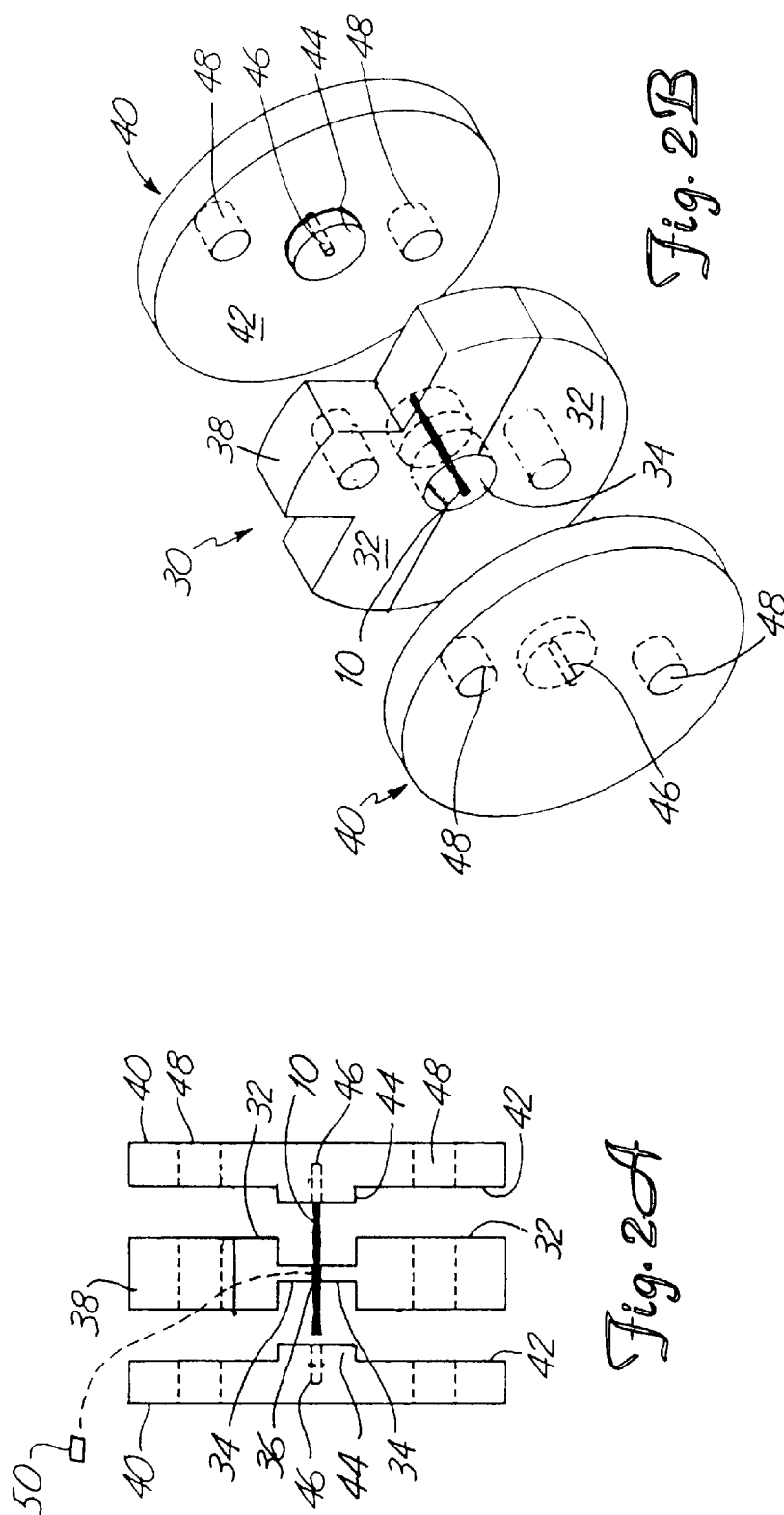
Fig. 1A

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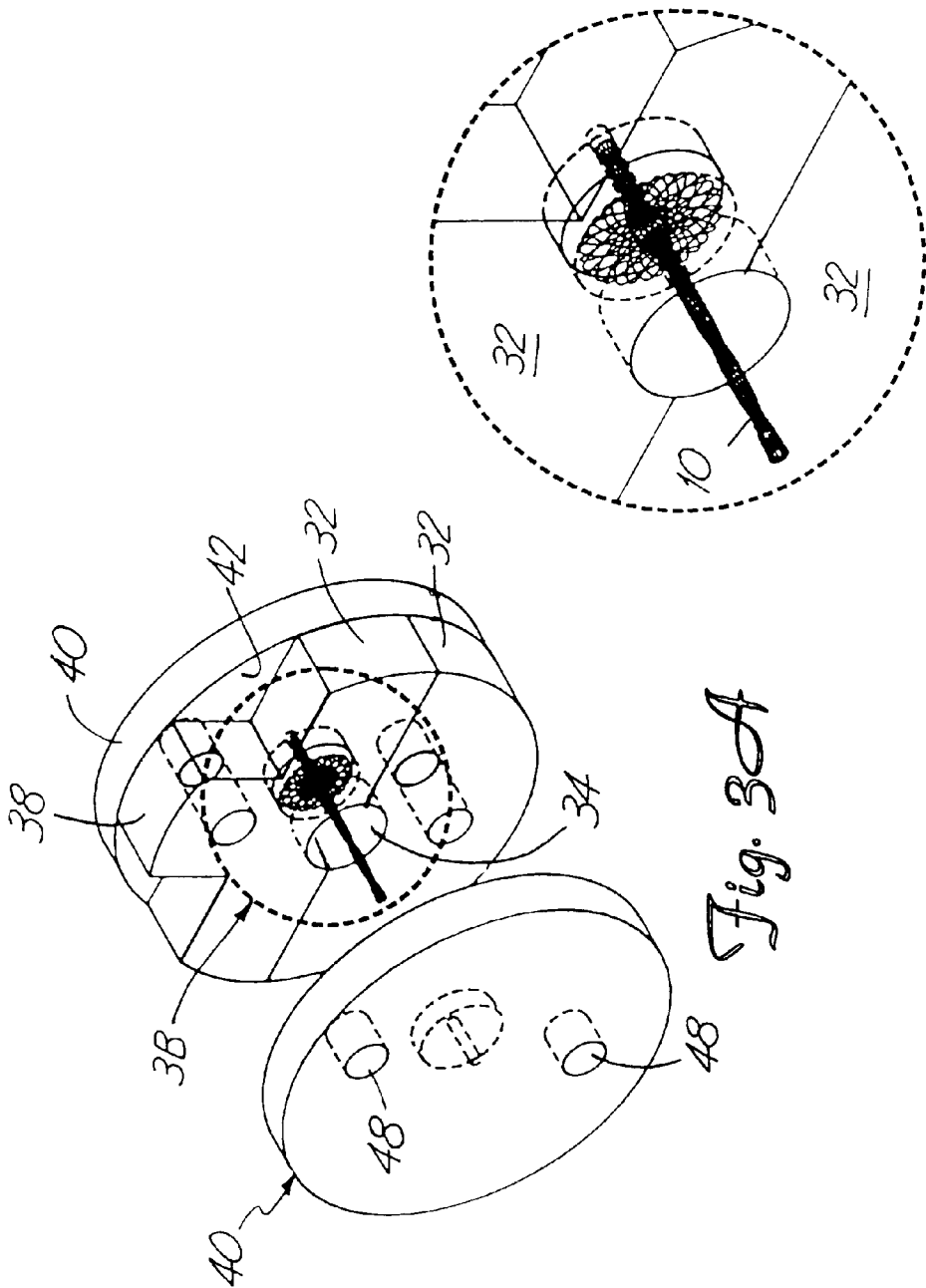


Fig. 3B

Fig. 3A

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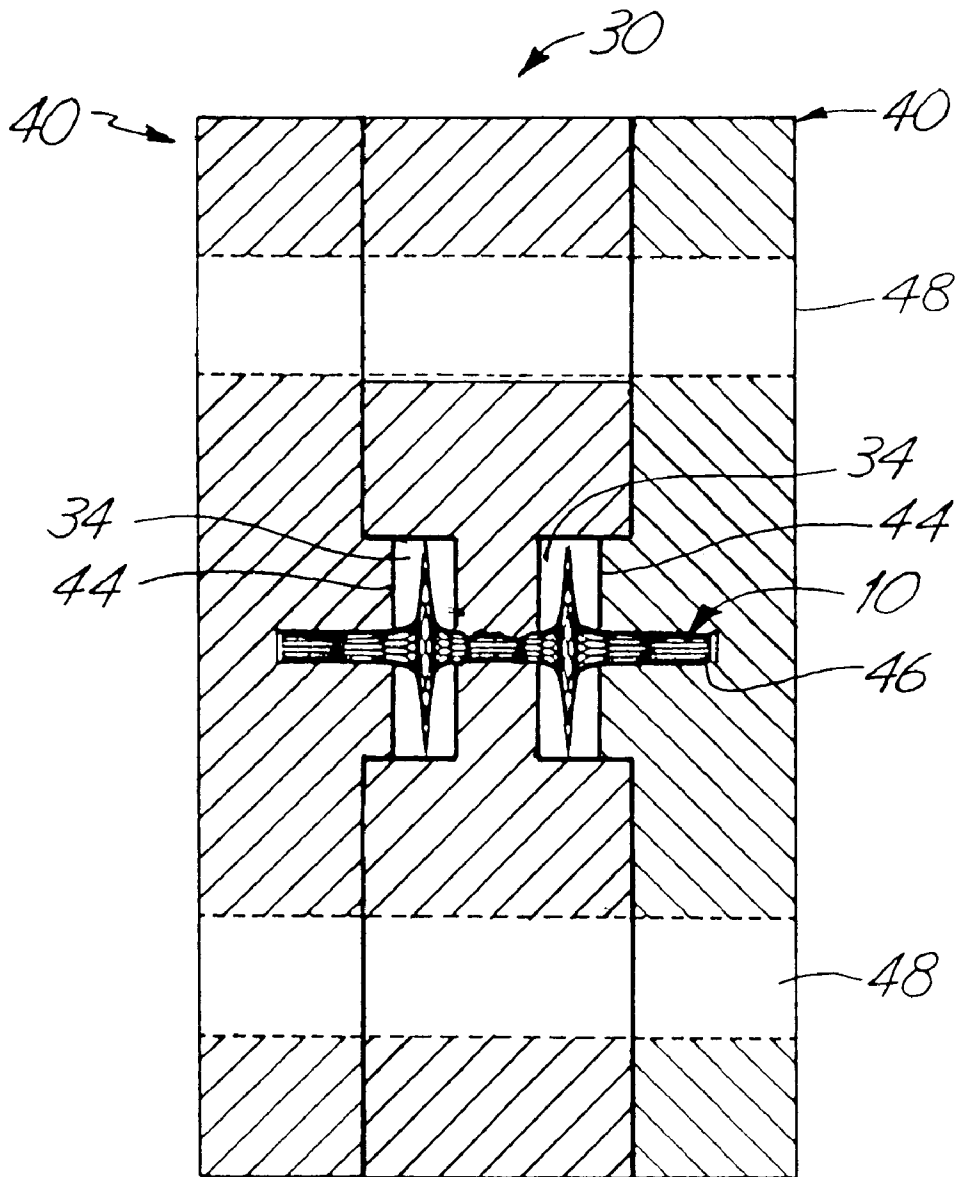


Fig. 4

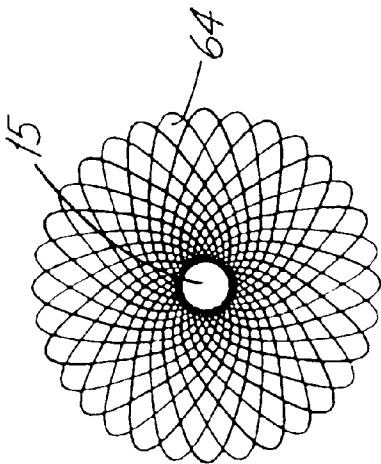


Fig. 5B

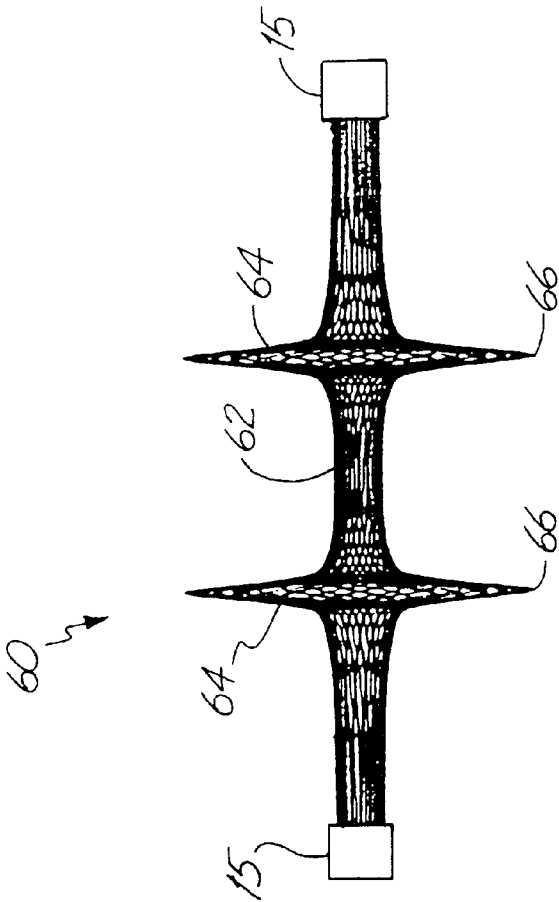


Fig. 5A

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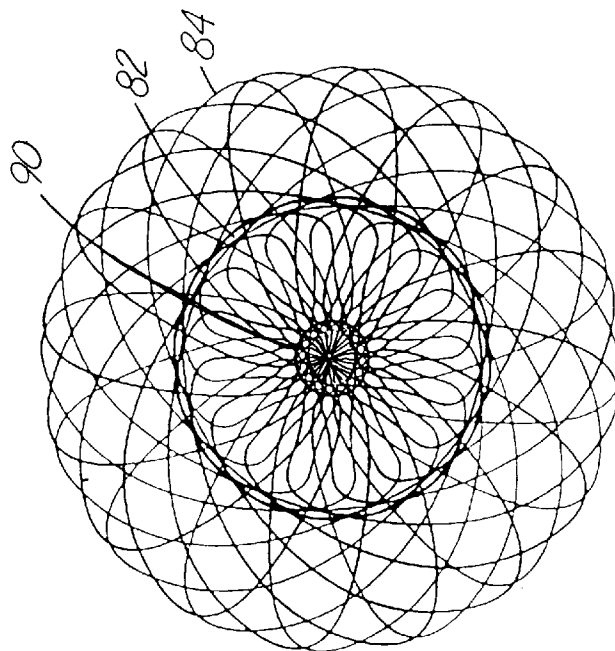


Fig. 6B

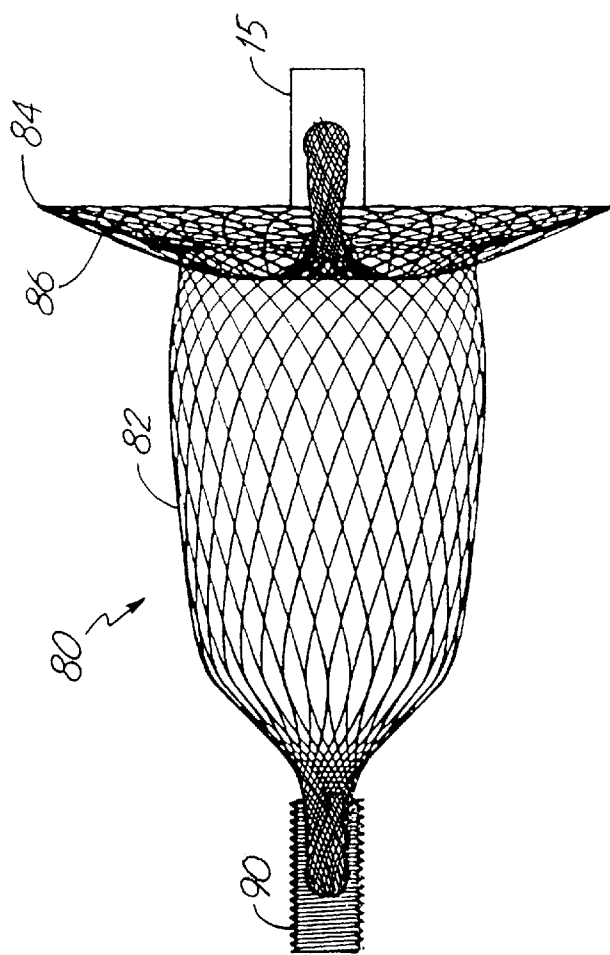
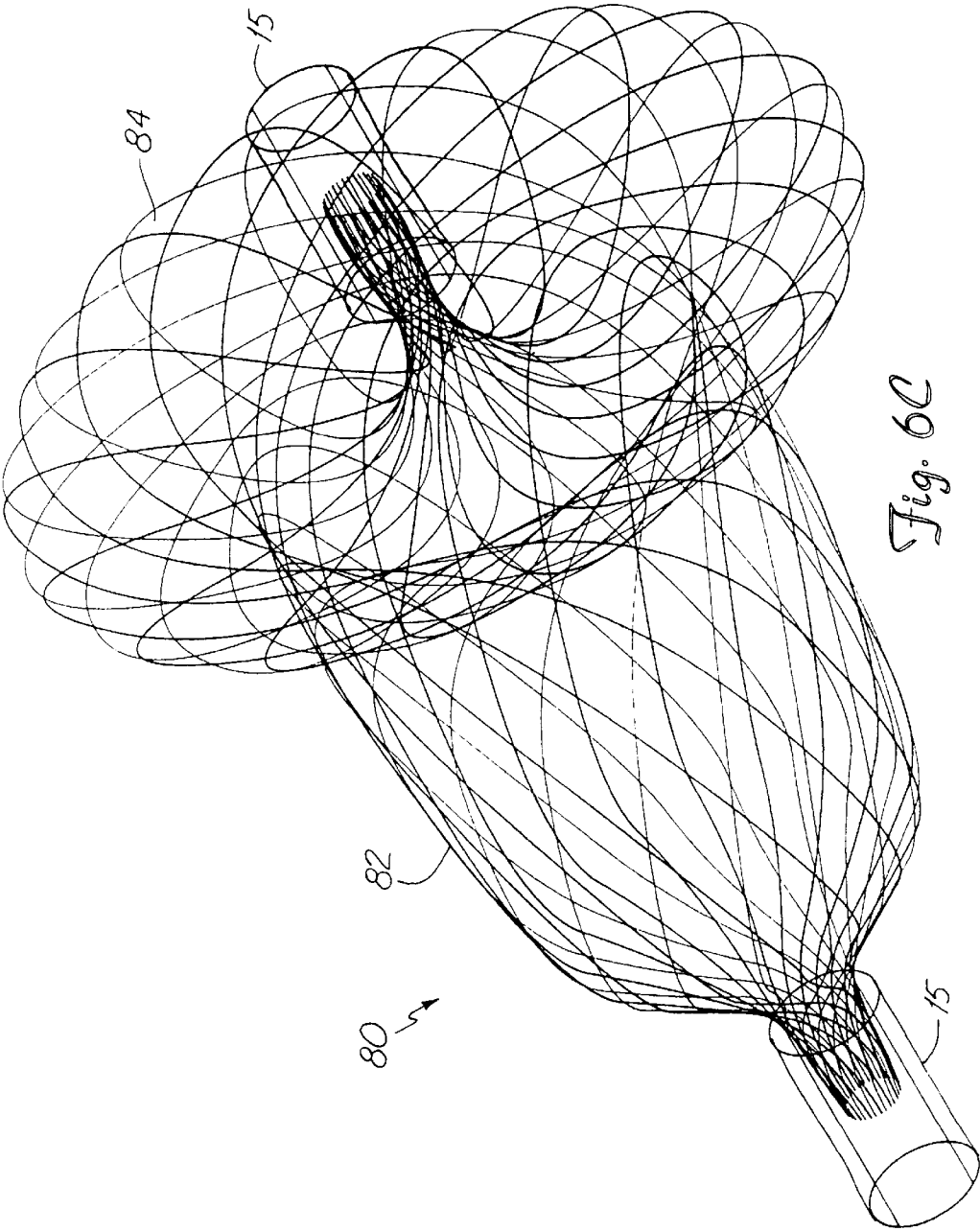
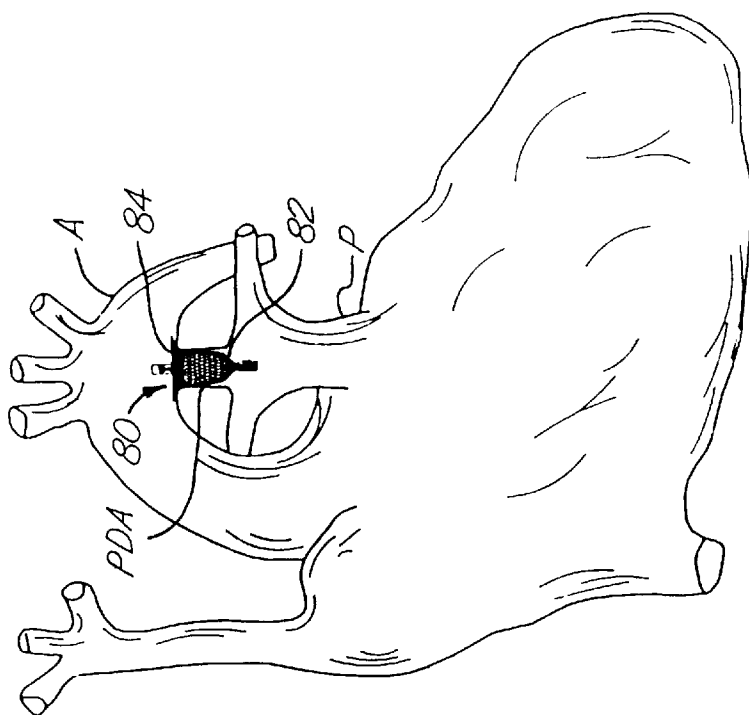
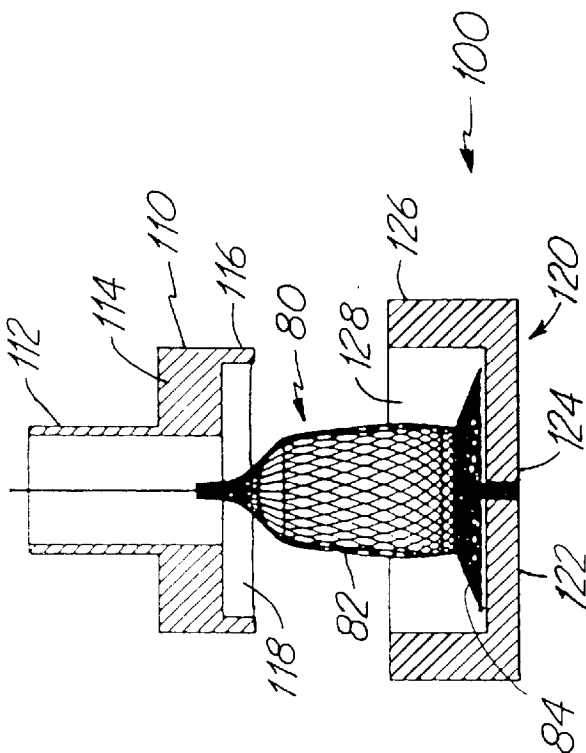
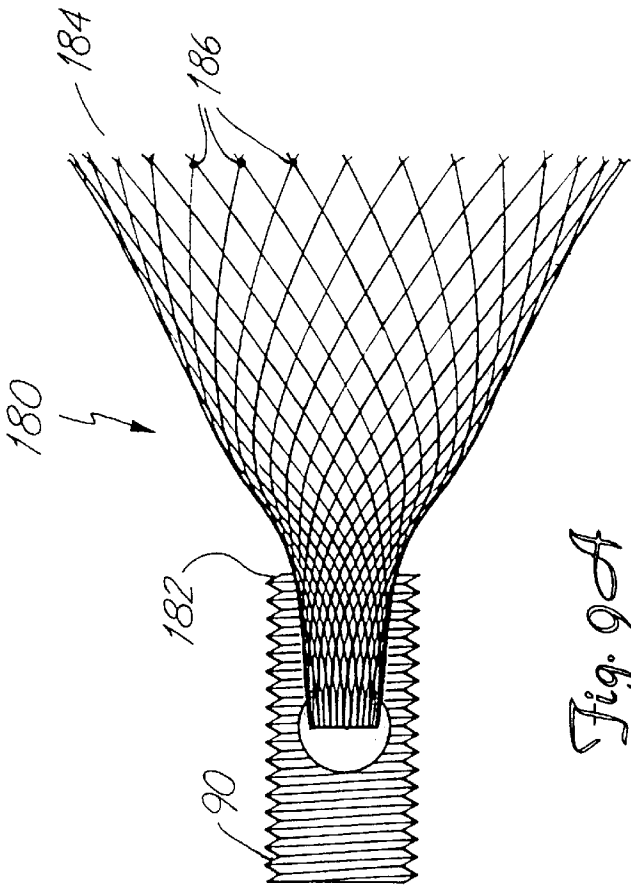
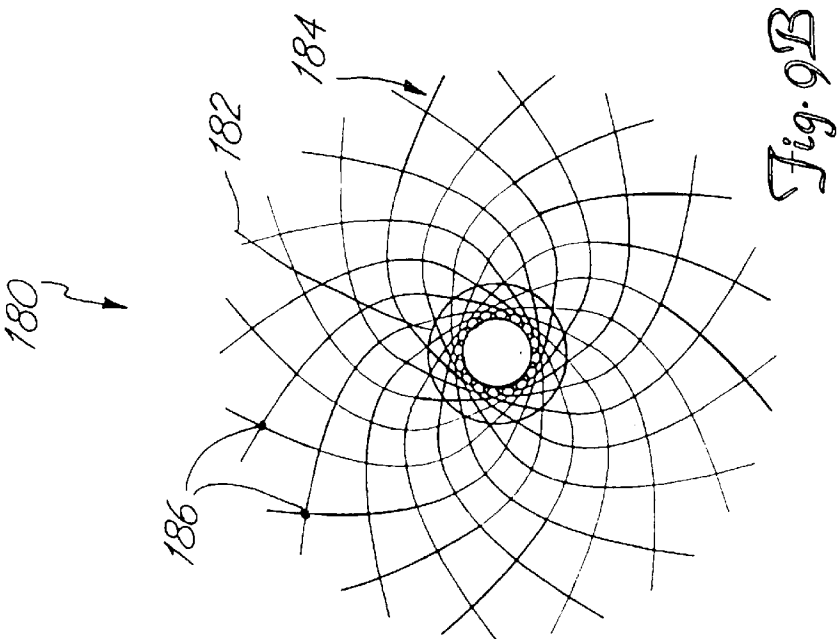


Fig. 6A







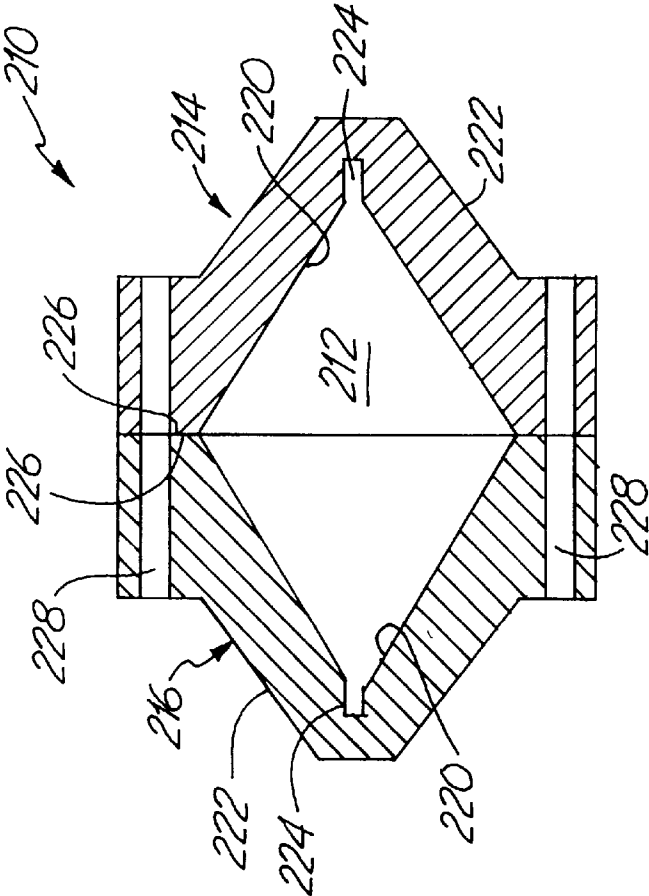


Fig. 10B

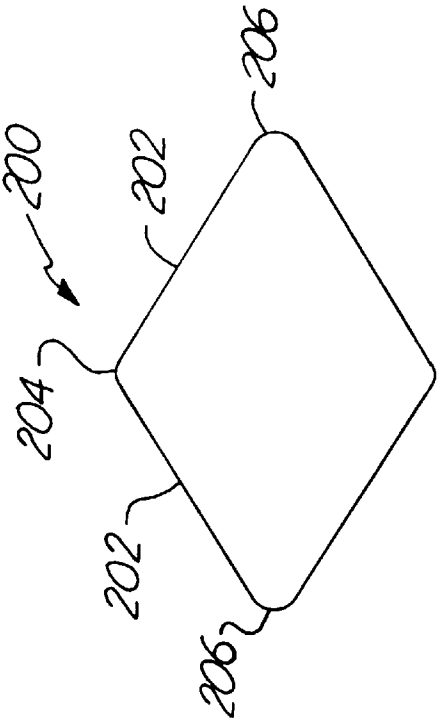


Fig. 10A

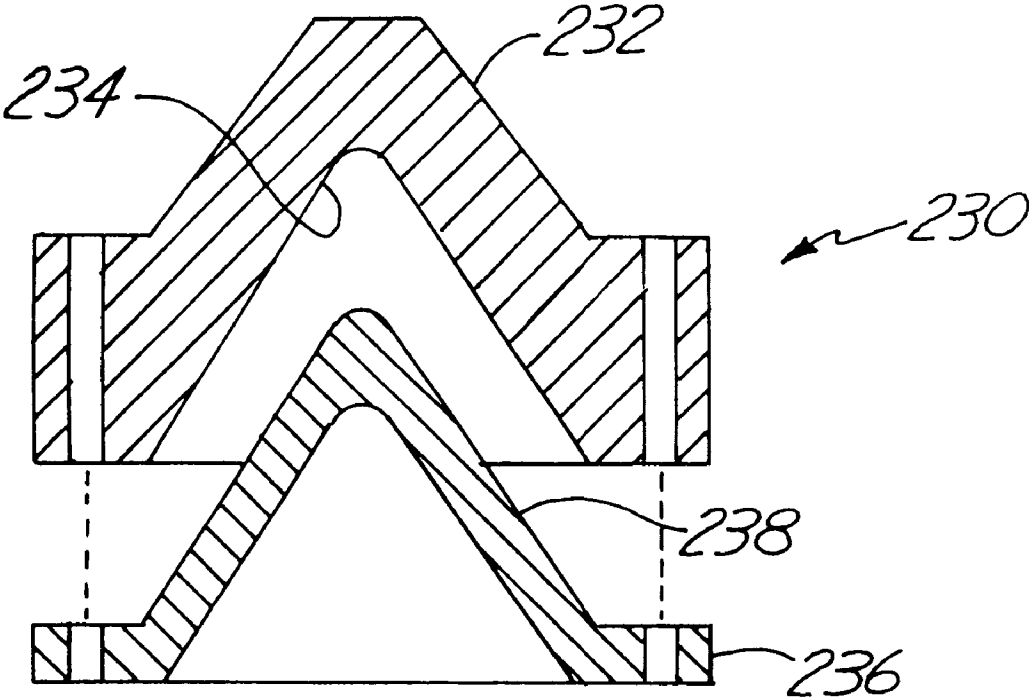


Fig. 10 C

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**METHOD OF FORMING MEDICAL  
DEVICES; INTRAVASCULAR OCCLUSION  
DEVICES**

**FIELD OF THE INVENTION**

The present invention generally relates to intravascular devices for treating certain medical conditions and, more particularly, provides a method of forming intravascular devices and certain novel intravascular occlusion devices. The devices made in accordance with the invention are particularly well suited for delivery through a catheter or the like to a remote location in a patient's vascular system or in analogous vessels within a patient's body.

**BACKGROUND OF THE INVENTION**

A wide variety of intravascular devices are used in various medical procedures. Certain intravascular devices, such as catheters and guidewires, are generally used simply to deliver fluids or other medical devices to specific locations within a patient's body, such as a selective site within the vascular system. Other, frequently more complex, devices are used in treating specific conditions, such as devices used in removing vascular occlusions or for treating septal defects and the like.

In certain circumstances, it may be necessary to occlude a patient's vessel, such as to stop blood flow through an artery to a tumor or other lesion. Presently, this is commonly accomplished simply by inserting, e.g. Ivalon particles, a trade name for vascular occlusion particles, and short sections of coil springs into a vessel at a desired location. These "embolization agents" will eventually become lodged in the vessel, frequently floating downstream of the site at which they are released before blocking the vessel. In part due to the inability to precisely position the embolization agents, this procedure is often limited in its utility.

Detachable balloon catheters are also used to block patients' vessels. When using such a catheter, an expandable balloon is carried on a distal end of a catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place.

Such balloon embolizations are also prone to certain safety problems, though. For example, if the balloon is not filled enough, it will not be firmly fixed in the vessel and may drift downstream within the vessel to another location, much like the loose embolization agents noted above. In order to avoid this problem, physicians may overfill the balloons; it is not uncommon for balloons to rupture and release the resin into the patient's bloodstream.

Mechanical embolization devices, filters and traps have been proposed in the past. Even if some of those devices have proven effective, they tend to be rather expensive and time-consuming to manufacture. For example, some intravascular blood filters suggested by others are formed of a plurality of specially-shaped legs which are adapted to fill the vessel and dig into the vessel walls. In making most such filters, the legs must be individually formed and then painstakingly attached to one another, frequently entirely by hand, to assemble the final filter. Not only does this take significant skilled manpower, and hence increase the costs of such devices, the fact that each item must be made by hand tends to make quality control more difficult. This same difficulty and expense of manufacturing is not limited to such filters, but is experienced in many other intravascular devices as well.

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Accordingly, it would be desirable to provide a method for forming devices for deployment in a vessel in a patient's body which is both economical and yields consistent, reproducible results. It would also be advantageous to provide a reliable embolization device which is both easy to deploy and can be accurately placed in a vessel.

**SUMMARY OF THE INVENTION**

The present invention provides a method for forming intravascular devices from a resilient metal fabric and medical devices which can be formed in accordance with this method. In the method of the invention, a metal fabric formed of a plurality of resilient strands is provided, with the wires being formed of a resilient material which can be heat treated to substantially set a desired shape. This fabric is then deformed to generally conform to a molding surface of a molding element and the fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The fabric so treated defines an expanded state of a medical device which can be deployed through a catheter into a channel in a patient's body.

In accordance with the method of the invention, a distal end of a catheter can be positioned in a channel in a patient's body to position the distal end of the catheter adjacent a treatment site for treating a physiological condition. A medical device made in accordance with the process outlined above can be collapsed and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon it will tend to return to its expanded state adjacent the treatment site.

Further embodiments of the present invention also provide specific medical devices which may be made in accordance with the present invention. Such devices of the invention are formed of a metal fabric and have an expanded configuration and a collapsed configuration. The devices are collapsed for deployment through a catheter and, upon exiting the distal end of the catheter in a patient's channel, will resiliently substantially return to their expanded configuration. In accordance with a first of these embodiments, a generally elongate medical device has a generally tubular middle portion and a pair of expanded diameter portions, with one expanded diameter portion positioned at either end of the middle portion. In another embodiment, the medical device is generally bell-shaped, having an elongate body having a tapered first end and a larger second end, the second end presenting a fabric disc which will be oriented generally perpendicular to an axis of a channel when deployed therein.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIGS. 1A and 1B each depict a metal fabric suitable for use with the invention;

FIGS. 2A and 2B are a side view and a perspective view, respectively, of a molding element and a length of a metal fabric suitable for use in forming a medical device in accordance with the invention, the mold being in a disassembled state;

FIG. 3A is a perspective view showing the molding element and metal fabric of FIG. 2 in a partially assembled state;

FIG. 3B is a close-up view of the highlighted area of FIG. 3A showing the compression of the metal fabric in the molding element;

FIG. 4 is a cross-sectional view showing the molding element and metal fabric of FIG. 2 in an assembled state;

FIGS. 5A and 5B are a side view and an end view, respectively, of a medical device in accordance with the invention;

FIGS. 6A–6C are a side view, an end view and a perspective view, respectively, of a medical device in accordance with another embodiment of the invention;

FIG. 7 is a side, cross sectional view of a molding element suitable for forming the medical device shown in FIGS. 6A–6C;

FIG. 8 is a schematic illustration showing the device of FIGS. 6A–6C deployed in a channel of a patient's vascular system to occlude a Patent Ductus Arteriosus;

FIGS. 9A and 9B are a side view and an end view, respectively, of a medical device in accordance with yet another embodiment of the invention;

FIG. 10A is a side view of one molding element suitable for forming the invention of FIGS. 9A and 9B;

FIG. 10B is a cross-sectional view of another molding element suitable for forming the invention of FIGS. 9A and 9B;

FIG. 10C is a cross-sectional view of still another molding element suitable for forming the invention of FIGS. 9A and 9B;

DETAILED DESCRIPTION OF THE  
PREFERRED EMBODIMENTS

The present invention provides a reproducible, relatively inexpensive method of forming devices for use in channels in patients' bodies, such as vascular channels, urinary tracts, biliary ducts and the like, as well as devices which may be made via that method. In forming a medical device via the method of the invention, a metal fabric 10 is provided. The fabric is formed of a plurality of wire strands having a predetermined relative orientation between the strands. FIGS. 1A and 1B illustrate two examples of metal fabrics which are suitable for use in the method of the invention.

In the fabric of FIG. 1A, the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid. Such tubular braids are well known in the fabric arts and find some applications in the medical device field as tubular fabrics, such as in reinforcing the wall of a guiding catheter. As such braids are well known, they need not be discussed at length here.

The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) may be adjusted as desired for a particular application. For example, if the medical device to be formed is to be used to occlude the channel in which it is placed, the pitch and pick of the fabric will tend to be higher than if the device is simply intended to filter bodily fluid passing therethrough.

For example, in using a tubular braid such as that shown in FIG. 1A to form a device such as that illustrated in FIGS. 5A and 5B, a tubular braid of about 4 mm in diameter with a pitch of about 50° and a pick of about 74 (per linear inch) would seem suitable for a devices used in occluding channels on the order of about 2 mm to about 4 mm in inner diameter, as detailed below in connection with the embodiment of FIGS. 5A and 5B.

FIG. 1B illustrates another type of fabric which is suitable for use in the method of the invention. This fabric is a more

conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like. In the woven fabric shown in FIG. 1B, there are also two sets 14 and 14' of generally parallel strands, with one set of strands being oriented at an angle, e.g. generally perpendicular (having a pick of about 90°), with respect to the other set. As noted above, the pitch and pick of this fabric (or, in the case of a knit fabric, the pick and the pattern of the kit, e.g. Jersey or double knits) may be selected to optimize the desired properties of the final medical device.

The wire strands of the metal fabric used in the present method should be formed of a material which is both resilient and can be heat treated to substantially set a desired shape. Materials which are believed to be suitable for this purpose include a cobalt-based low thermal expansion alloy referred to in the field as Elgiloy, nickel-based high-temperature high-strength "superalloys" commercially available from Haynes International under the trade name Hastelloy, nickel-based heat treatable alloys sold under the name Incoloy by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wires is that the wires retain a suitable amount of the deformation induced by the molding surface (as described below) when subjected to a predetermined heat treatment.

One class of materials which meet these qualifications are so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

One particularly preferred shape memory alloy for use in the present method is nitinol, an approximately stoichiometric alloy of nickel and titanium, which may also include other minor amounts of other metals to achieve desired properties. NiTi alloys such as nitinol, including appropriate compositions and handling requirements, are well known in the art and such alloys need not be discussed in detail here. For example, U.S. Pat. No. 5,067,489 (Lind) and U.S. Pat. No. 4,991,602 (Amplatz et al.), the teachings of which are incorporated herein by reference, discuss the use of shape memory NiTi alloys in guidewires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic—they are said to be "superelastic" or "pseudoelastic". This elasticity will help a device of the invention return to a present expanded configuration for deployment.

The wire strands can comprise a standard monofilament of the selected material, i.e. a standard wire stock may be used. If so desired, though, the individual wire strands may be formed from "cables" made up of a plurality of individual wires. For example, cables formed of metal wires where several wires are helically wrapped about a central wire are commercially available and NiTi cables having an outer diameter of 0.003 inches or less can be purchased. One advantage of certain cables is that they tend to be "softer" than monofilament wires having the same diameter and formed of the same material. Additionally, if the device being formed from the wire strands is to be used to occlude a vessel, the use of a cable can increase the effective surface area of the wire strand, which will tend to promote thrombosis.

In preparation of forming a medical device in keeping with the invention, an appropriately sized piece of the metal

fabric is cut from the larger piece of fabric which is formed, for example, by braiding wire strands to form a long tubular braid. The dimensions of the piece of fabric to be cut will depend, in large part, upon the size and shape of the medical device to be formed therefrom.

When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual wire strands will tend to return to their heat-set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more economical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device, as noted below.

In such untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of braid cut to form the device are constrained relative to one another. One method which has proven to be useful to prevent the braid from unraveling is to clamp the braid at two locations and cut the braid to leave a length of the braid having clamps (15 in FIG. 2) at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps 15 will hold the ends of the cut braid together and prevent the braid from unraveling.

Alternatively, one can solder, braze, weld or otherwise affix the ends of the desired length together (e.g. with a biocompatible cementitious organic material) before cutting the braid. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder.

The same problems present themselves when a flat sheet of fabric such as the woven fabric shown in FIG. 1B is used. With such a fabric, the fabric can be inverted upon itself to form a recess or depression and the fabric can be clamped about this recess to form an empty pocket (not shown) before the fabric is cut. If it is desired to keep the fabric in a generally flat configuration, it may be necessary to weld the junctions of the strands together adjacent the periphery of the desired piece of fabric before that piece is cut from the larger sheet. So connecting the ends of the strands together will prevent fabrics formed of untreated shape memory alloys and the like from unraveling during the forming process.

Once an appropriately sized piece of the metal fabric is obtained, the fabric is deformed to generally conform to a surface of a molding element. As will be appreciated more fully from the discussion below in connection with FIGS. 2-10, so deforming the fabric will reorient the relative positions of the strands of the metal fabric from their initial order to a second, reoriented configuration. The shape of the molding element should be selected to deform the fabric into substantially the shape of the desired medical device.

The molding element can be a single piece, or it can be formed of a series of mold pieces which together define the surface to which the fabric will generally conform. The molding element can be positioned within a space enclosed by the fabric or can be external of such a space, or can even be both inside and outside such a space.

In order to illustrate one example of how such a mold may be configured and how it may be used in accordance with the method of the invention, reference will be had to FIGS. 2-5. In FIGS. 2-4, the molding element 20 is formed of a number of separate pieces which can be attached to one another to

complete the molding element 20. In using such a multi-piece molding element, the mold can be assembled about the cut length of fabric 10, thereby deforming the fabric to generally conform to the desired surface (or surfaces) of the molding element.

In the molding element illustrated in FIGS. 2-4, the metal fabric 10 is deformed to generally conform to a surface of the molding element 20, the molding element comprising a center section 30 and a pair of end plates 40. Turning first to the center section 30, the center section is desirably formed of opposed halves 32, 32 which can be moved away from one another in order to introduce the metal fabric 10 into the mold. Although these two halves 32, 32 are shown in the drawings as being completely separated from one another, it is to be understood that these halves could be interconnected, such as by means of a hinge or the like, if so desired. The opposed halves of the molding element 20 shown in the drawings of FIGS. 2 and 3 each include a pair of semi-circular recesses opposed on either side of a ridge defining a generally semi-circular opening. When the two halves are assembled in forming the device, as best seen in FIG. 3, the semi-circular openings in the opposed halves 32, 32 mate to define a generally circular forming port 36 passing through the center section 30. Similarly, the semi-circular recesses in the two halves together form a pair of generally circular central recesses 34, with one such recess being disposed on either face of the center section.

The overall shape and dimensions of the center section can be varied as desired; it is generally the size of the central recesses 34 and the forming port 36 which will define the size and shape of the middle of the finished device, as explained below. If so desired, each half 32 may be provided with a manually graspable projection 38. In the embodiment shown in the drawings, this projection 38 is provided at a location disposed away from the abutting faces of the respective halves. Such a manually graspable projection 38 will simply enable an operator to more easily join the two halves to define the recesses 34 and forming port 36.

The center section is adapted to cooperatively engage a pair of end plates 40 for forming the desired device. In the embodiment shown in FIGS. 2 and 3, the center section 30 has a pair of flat outer faces 39 which are each adapted to be engaged by an inner face 42 of one of the two end plates 40. Each end plate includes a compression disk 44 which extends generally laterally inwardly from the inner face 42 of the end plate. This compression disk 44 should be sized to permit it to be received within one of the central recesses 34 on either face of the center section 30. For reasons explained more fully below, each compression disk 44 includes a cavity 46 for receiving an end of the length of the metal fabric 10.

One or more channels 48 for receiving bolts and the like may also be provided through each of the end plates and through the center section 30. By passing bolts through these channels 48, one can assemble the molding element 20 and retain the metal fabric in the desired shape during the heat treatment process, as outlined below.

In utilizing the molding element 20 shown in FIGS. 2-4, a length of the metal fabric 10 can be positioned between the opposed halves 32 of the center section 30. In the drawings of the molding element 20 of FIGS. 2-4, the metal fabric 10 is a tubular braid such as that illustrated in FIG. 1A. A sufficient length of the tubular braid should be provided to permit the fabric to conform to the molding surface, as explained below. Also, as noted above, care should be taken to secure the ends of the wire strands defining the tubular braid in order to prevent the metal fabric from unraveling.

A central portion of the length of the metal braid may be positioned within one of the two halves of the forming port 36 and the opposed halves 32 of the center section may be joined to abut one another to restrain a central portion of the metal braid within the central forming port 36 through the center section.

The tubular braid will tend to have a natural, relaxed diameter which is defined, in large part, when the tubular braid is formed. Unless the tubular braid is otherwise deformed, when the wire strands are in their relaxed state they will tend to define a generally hollow tube having the predetermined diameter. The outer diameter of the relaxed braid may be, for example, about 4 mm. The relative size of the forming port 36 in the central section 30 of the molding element and the natural, relaxed outer diameter of the tubular braid may be varied as desired to achieve the desired shape of the medical device being formed.

In the embodiment shown in FIGS. 2 and 3, the inner diameter of the forming port 36 is optimally slightly less than the natural, relaxed outer diameter of the tubular braid 10. Hence, when the two halves 32, 32 are assembled to form the center section 30, the tubular braid 10 will be slightly compressed within the forming port 36. This will help ensure that the tubular braid conforms to the inner surface of the forming port 36, which defines a portion of the molding surface of the molding element 20.

If so desired, a generally cylindrical internal molding section (not shown) may also be provided. This internal molding section has a slightly smaller diameter than the inner diameter of the forming port 36. In use, the internal molding section is placed within the length of the metal fabric, such as by manually moving the wire strands of the fabric apart to form an opening through which the internal molding section can be passed. This internal molding section should be positioned within the tubular braid at a location where it will be disposed within the forming port 36 of the center section when the molding element is assembled. There should be a sufficient space between the outer surface of the interior molding section and the inner surface of the forming port 36 to permit the wire strands of the fabric 10 to be received therebetween.

By using such an internal molding section, the dimensions of the central portion of the finished medical device can be fairly accurately controlled. Such an internal molding section may be necessary in circumstances where the natural, relaxed outer diameter of the tubular braid 10 is less than the inner diameter of the forming port 36 to ensure that the braid conforms to the inner surface of that forming port. However, it is not believed that such an internal molding section would be necessary if the natural, relaxed outer diameter of the braid were larger than the inner diameter of the forming port 36.

As noted above, the ends of the tubular braid should be secured in order to prevent the braid from unraveling. Each end of the metal fabric 10 is desirably received within a cavity 46 formed in one of the two end plates 40. If a clamp (15 in FIG. 2) is used, the clamp may be sized to be relatively snugly received within one of these cavities 46 in order to effectively attach the end of the fabric to the end plate 40. The end plates can then be urged toward the center section 30 and toward one another until the compression disk 44 of each end plate is received within a central recess 34 of the center section 30. The molding element may then be clamped in position by passing bolts or the like through the channels 48 in the molding element and locking the various components of the molding element together by tightening a nut down onto such a bolt (not shown).

As best seen in FIG. 3A, when an end plate is urged toward the center section 30, this will compress the tubular braid 10 generally along its axis. When the tubular braid is in its relaxed configuration, as illustrated in FIG. 1A, the wire strands forming the tubular braid will have a first, predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis, as illustrated in FIG. 4. When the fabric is so deformed, the relative orientation of the wire strands of the metal fabric will change. When the molding element is finally assembled, the metal fabric will generally conform to the molding surface of this element.

In the molding element 20 shown in FIGS. 2-4, the molding surface is defined by the inner surface of the forming port, the inner surfaces of the central recess 34 and the faces of the compression disks 44 which are received within the recesses 34. If an internal molding section is used, the cylindrical outer surface of that section may also be considered a part of the molding surface of the molding element 20. Accordingly, when the molding element 20 is completely assembled the metal fabric will tend to assume a somewhat "dumbbell"-shaped configuration, with a relatively narrow center section disposed between a pair of bulbous, perhaps even disk-shaped end sections, as best seen in FIG. 4.

It should be understood that the specific shape of the particular molding element 20 shown in FIGS. 2-4 is intended to produce one useful medical device in accordance with the present method, but that other molding elements having different configurations could also be used. If a more complex shape is desired, the molding element may have more parts, but if a simpler shape is being formed the molding element may have even fewer parts. The number of parts in a given molding element and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device as the molding element must define a molding surface to which the metal fabric will generally conform.

Accordingly, the specific molding element 20 shown in FIGS. 2-4 is simply intended as one specific example of a suitable molding element for forming one particular useful medical device. Additional molding elements having different designs for producing different medical devices are explained below in connection with, e.g., FIGS. 8 and 10. Depending on the desired shape of the medical device being formed, the shape and configuration of other specific molding elements can be readily designed by those of ordinary skill in the art.

Once the molding element 20 is assembled with the metal fabric generally conforming to a molding surface of that element, the fabric can be subjected to a heat treatment while it remains in contact with that molding surface. This heat treatment will depend in large part upon the material of which the wire strands of the metal fabric are formed, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface.

The time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire stands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the

fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a "superelastic" or "pseudoelastic" phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal when in its austenitic phase can be set. This will tend to "set" the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

Suitable heat treatments of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils, for example, are used in a number of medical applications, such as in forming the coils commonly carried around distal lengths of guidewires. A wide body of knowledge exists for forming nitinol in such medical devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention.

Briefly, though, it has been found that holding a nitinol fabric at about 500° C. to about 550° C. for a period of about 1 to about 30 minutes, depending on the softness or harness of the device to be made, will tend to set the fabric in its deformed state, i.e. wherein it conforms to the molding surface of the molding element. At lower temperatures the heat treatment time will tend to be greater (e.g. about one hour at about 350° C.) and at higher temperatures the time will tend to be shorter (e.g. about 30 seconds at about 900° C.). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors which will be well known to those skilled in this field.

Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. In the present invention, this can be accomplished by, for example, hooking electrodes to the clamps 15 carried at either end of the metal fabric illustrated in FIG. 5. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire molding element to the desired heat treating temperature in order to heat the metal fabric to the desired temperature.

After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in a deformed state. When the molding element 20 illustrated in FIGS. 2-4 is used, the bolts (not shown) may be removed and the various parts of the molding element may be disassembled in essentially the reverse of the process of assembling the molding element. If an internal molding section is used, this molding section can be removed in much the same fashion that it is placed within the generally tubular metal fabric in assembling the molding element 20, as detailed above.

FIGS. 5A and 5B illustrate one embodiment of a medical device 60 which may be made using the molding element 20 of FIGS. 2-4. As discussed below, the device of FIG. 5 is particularly well suited for use in occluding a channel within a patient's body and these designs have particular advantages in use as vascular occlusion devices.

The vascular occlusion device 60 of FIG. 6A includes a generally tubular middle portion 62 and a pair of expanded diameter portions 64. One expanded diameter portion is disposed at either end of the generally tubular middle portion 62. In the embodiment shown in FIGS. 5A and 5B, the expanded diameter portions 64 include a ridge 66 positioned about midway along their lengths.

The relative sizes of the tubular middle section and the expanded diameter portions can be varied as desired. In this particular embodiment, the medical device is intended to be used as a vascular occlusion device to substantially stop the flow of blood through a patient's blood vessel. When the device 60 is deployed within a patient's blood vessel, as detailed below, it will be positioned within the vessel such that its axis generally coincides with the axis of the vessel. The dumbbell-shape of the present device is intended to limit the ability of the vascular occlusion device 60 to turn at an angle with respect to the axis of the blood vessel to ensure that it remains in substantially the same position in which the operator deploys it within the vessel.

Although the illustrated embodiments of this invention only have two expanded diameter portions, it should be understood that the device could have more than two such expanded diameter portions. For example, if the device has three expanded diameter portions, each expanded diameter portion is separated from at least one other expanded diameter portion by a tubular portion having a smaller diameter. If so desired, the diameters of each of the expanded diameter portions can be the same, but they need not be the same.

In order to relatively strongly engage the lumen of the blood vessel, the maximum diameter of the expanded diameter portions 64 (which occurs along the middle ridge 66 in this embodiment) should be selected so that it is at least as great as the diameter of the lumen of the vessel in which it is to be deployed, and is optimally slightly greater than that diameter. When it is deployed within the patient's vessel, the vascular occlusion device 60 will engage the lumen at two spaced-apart locations. The device 60 is desirably longer along its axis than the dimension of its greatest diameter. This will substantially prevent the vascular occlusion device 60 from turning within the lumen at an angle to its axis, essentially preventing the device from becoming dislodged and tumbling along the vessel with blood flowing through the vessel.

The relative sizes of the generally tubular middle portion 62 and expanded diameter portion 64 of the vascular occlusion device 60 can be varied as desired for any particular application. For example, the outer diameter of the middle portion 62 may range between about one quarter and about one third of the maximum diameter of the expanded diameter portions 64 and the length of the middle portion 62 may comprise about 20% to about 50% of the overall length of the device. Although these dimensions are suitable if the device 60 is to be used solely for occluding a vascular vessel, it is to be understood that these dimensions may be varied if the device is to be used in other applications, such as where the device is intended to be used simply as a vascular filter rather than to substantially occlude the entire vessel or where the device is deployed in a different channel in a patient's body.

The aspect ratio (i.e., the ratio of the length of the device over its maximum diameter or width) of the device 60 illustrated in FIGS. 5A and 5B is desirably at least about 1.0, with a range of about 1.0 to about 3.0 being preferred and an aspect ratio of about 2.0 being particularly preferred. Having a greater aspect ratio will tend to prevent the device from rotating generally perpendicularly to its axis, which may be referred to as an end over end roll. So long as the outer diameter of the expanded diameter portions 64 of the device is large enough to seat the device fairly securely against the lumen of the channel in which the device is deployed, the inability of the device to turn end over end will help keep the device deployed precisely where it is positioned within the patient's vascular system or in any other channel in the

patient's body. Alternatively, having expanded diameter portions which have natural, relaxed diameters substantially larger than the lumen of the vessels in which the device is deployed should also suffice to wedge the device into place in the vessel without undue concern being placed on the aspect ratio of the device.

The pick and pitch of the metal fabric **10** used in forming the device **60**, as well as some other factors such as the number of wires employed in a tubular braid, are important in determining a number of the properties of the device. For example, the greater the pick and pitch of the fabric, and hence the greater the density of the wire strands in the fabric, the stiffer the device will be. Having a greater wire density will also provide the device with a greater wire surface area, which will generally enhance the tendency of the device to occlude a blood vessel in which it is deployed. This thrombogenicity can be either enhanced, e.g. by a coating of a thrombolytic agent or by attaching silk or wool fabric to the device, or abated, e.g. by a coating of a lubricious, anti-thrombogenic compound. A variety of materials and techniques for enhancing or reducing thrombogenicity are well known in the art and need not be detailed here.

When the device is deployed in a patient's vessel, thrombi will tend to collect on the surface of the wires. By having a greater wire density, the total surface area of the wires will be increased, increasing the thrombolytic activity of the device and permitting it to relatively rapidly occlude the vessel in which it is deployed. It is believed that forming the occlusion device **60** from a 4 mm diameter tubular braid having a pick of at least about 40 and a pitch of at least about 30° will provide sufficient surface area to substantially completely occlude a blood vessel of 2 mm to about 4 mm in inner diameter in a suitable period of time. If it is desired to increase the rate at which the device **60** occludes the vessel in which it is deployed, any of a wide variety of known thrombolytic agents can be applied to the device.

FIGS. 6A–6C illustrate an alternative embodiment of a medical device in accordance with the present invention. This device **80** has a generally bell-shaped body **82** and an outwardly extending forward end **84**. One application for which this device is particularly well suited is occluding defects known in the art as patent ductus arteriosus (PDA). PDA is essentially a condition wherein two blood vessels, most commonly the aorta and pulmonary artery adjacent the heart, have a shunt between their lumens. Blood can flow directly between these two blood vessels through the shunt, compromising the normal flow of blood through the patient's vessels.

As explained more fully below in connection with FIG. 8, the bell-shaped body **82** is adapted to be deployed within the shunt between the vessels, while the forward end **84** is adapted to be positioned within one of the two vessels to help seat the body in the shunt. The sizes of the body **82** and the end **84** can be varied as desired for differently sized shunts. For example, the body may have a diameter along its generally cylindrical middle **86** of about 10 mm and a length along its axis of about 25 mm. In such a device, the base **88** of the body may flare generally radially outward until it reaches an outer diameter equal to that of the forward end **84**, which may be on the order of about 20 mm in diameter.

The base **88** desirably flares out relatively rapidly to define a shoulder tapering radially outwardly from the middle **86** of the body. When the device is deployed in a vessel, this shoulder will abut the lumen of one of the vessels being treated. The forward end **84** is retained within the vessel and urges the base **88** of the body open to ensure that

the shoulder engages the wall of the vessel to prevent the device **80** from becoming dislodged from within the shunt.

As detailed above, in making a device of the invention it is desirable to attach the ends of the wire strands forming the metal fabric **10** to one another to prevent the fabric from unraveling. In the illustrations of FIGS. 6A–6C, a clamp **15** is used to tie together the ends of the wire strands adjacent the front end **84** of the device. It is to be understood that this clamp **15** is simply a schematic illustration, though, and that the ends could be attached in other ways, such as by welding, soldering, brazing, use of a biocompatible cementitious material or in any other suitable fashion.

The rearward ends of the wire strands are shown as being attached to one another by an alternative clamping means **90**. This clamp **90** serves the same purpose as the schematically illustrated clamp **15**, namely to interconnect the ends of the wires. However the clamp **90** also serves to connect the device **80** to a delivery system (not shown). In the embodiment shown, the clamp **90** is generally cylindrical in shape and has a recess for receiving the ends of the wires to substantially prevent the wires from moving relative to one another, and a threaded outer surface. The threaded outer surface is adapted to be received within a cylindrical recess (not shown) on a distal end of a delivery device and to engage the threaded inner surface of the delivery device's recess.

The delivery device (not shown) can take any suitable shape, but desirably comprises an elongate, flexible metal shaft having such a recess at its distal end. The delivery device can be used to urge the PDA occlusion device **80** through the lumen of a catheter for deployment in a channel of the patient's body, as outlined below. When the device is deployed out the distal end of the catheter, the device will still be retained by the delivery device. Once the proper position of the device **80** in the shunt is confirmed, the shaft of the delivery device can be rotated about its axis to unscrew the clamp **90** from the recess in the delivery means.

By keeping the PDA device **80** attached to the delivery means, the operator could still retract the device for repositioning if it is determined that the device is not properly positioned in the first attempt. This threaded attachment will also allow the operator to control the manner in which the device **80** is deployed out of the distal end of the catheter. As explained below, when the device exits the catheter it will tend to resiliently return to a preferred expanded shape which is set when the fabric is heat treated. When the device springs back into this shape, it may tend to act against the distal end of the catheter, effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp **90** can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled and the operator can control the deployment to ensure proper positioning.

A PDA occlusion device **80** of this embodiment of the invention can advantageously be made in accordance with the method outlined above, namely deforming a metal fabric to generally conform to a molding surface of a molding element and heat treating the fabric to substantially set the fabric in its deformed state. FIG. 7 shows a molding element **100** which may be suitable for forming a PDA occlusion device **80** such as that shown in FIGS. 6A–6C.

The molding element **100** generally comprises a body portion **110** and an end plate **120**. The body portion **110** is

adapted to receive and form the body **82** of the device **80** while the end plate is adapted to compress against the metal fabric to form the forward end **84**. The body portion **110** includes an elongate, generally tubular central segment **112** which is sized to receive the elongate body **82** of the device. The central segment **112** of the molding element **100** opti-  
mally has an internal diameter slightly less than the natural, relaxed outer diameter of the tubular braid of which the device is formed. This compression of the braid will help yield devices with reproducibly sized bodies **82**. The forward end of the body portion **110** includes a back plate **114** which has a generally annular sidewall **116** depending downwardly therefrom. The sidewall defines a recess **118** which is generally circular in shape.

The end plate **120** of the molding element **100** has a generally disc-shaped face **122**, which desirably has a clamp port **124** approximately centered therein for receiving a clamp **15** attached to the metal fabric, as noted above. The end plate also has an annular sidewall **126** which extends generally upwardly from the face **122** to define a generally cylindrical recess **128** in the end plate **120**. The sidewall **116** of the body portion **110** is sized to be received within the recess **128** of the end plate.

In use, the metal fabric is placed in the molding element and the body portion **110** and the end plate **120** are brought toward one another. The inner face of the back plate **114** will engage the fabric and tend to urge it under compression generally radially outwardly. The fabric will then be enclosed generally within the recess **118** of the body portion and will generally conform to the inner surface of that recess. If one prevents the entire clamp **15** from passing through the clamp port **124**, the fabric will be spaced slightly away from the inner surface of the face **122**, yielding a slight dome shape in the forward end **84** of the device, as illustrated in FIG. 6. Although the illustrated embodiment includes such a dome-shaped forward end, it is to be understood that the forward end may be substantially flat (except for the clamp **15**), which can be accomplished by allowing the clamp to be received entirely within the clamp port **124** in the end plate.

Once the fabric is compressed in the molding element **100** so that it generally conforms to the molding surface of the molding element, the fabric can be subjected to a heat treatment such as is outlined above. When the molding element is opened again by moving the body portion **110** and the end plate **120** away from one another again, the fabric will generally retain its deformed, compressed configuration. The device can then be collapsed, such as by urging the clamps **15**, **90** generally axially away from one another, which will tend to collapse the device toward its axis. The collapsed device **80** can then be passed through a catheter for deployment in a channel in a patient's vascular system.

FIG. 8 schematically illustrates how a medical device **80** generally as outlined above can be used to occlude a patent ductus arteriosus. In this case, there is a shunt, referred to as a PDA above, which extends between a patient's aorta A and the pulmonary artery P. The device **80** can be passed through the PDA, such as by keeping the device collapsed within a catheter (not shown), and the forward end **84** of the device can be allowed to elastically expand to substantially recover its thermally set, "remembered" shape from the heat treatment process, such as by urging the device distally to extend beyond the distal end of the catheter. This forward end **84** should be larger than the lumen of the shunt of the PDA.

The device can then be retracted so that the forward end **84** engages the wall of the pulmonary artery P. If one

continues to retract the catheter, the engagement of the device with the wall of the pulmonary artery will tend to naturally pull the body portion **82** of the device from the catheter, which will permit the body portion to return to its expanded configuration. The body portion should be sized so that it will frictionally engage the lumen of the PDA's shunt. The device **80** will then be held in place by the combination of the friction between the body portion and the lumen of the shunt and the engagement between the wall of the pulmonary artery and the forward end **84** of the device. Over a relatively short period of time, thrombi will form in and on the device **80** and the thrombi will occlude the PDA. If so desired, the device may be coated with a suitable thrombolytic agent to speed up the occlusion of the PDA.

FIGS. 9A and 9B are a side view and an end view, respectively, of yet another embodiment of the present invention. This device **180** can be used for a variety of applications in a patient's blood vessels. For example, if a fabric having a relatively high pick (i.e. where the wire density is fairly great) is used in making the device, the device can be used to occlude blood vessels. In other applications, it may serve as a filter within a channel of a patient's body, either in a blood vessel or in another channel, such as in a urinary tract or biliary duct. In order to further enhance or reduce the device's tendency to occlude the vessel, depending on the application of the device a suitable known thrombogenic or antithrombogenic coating may be applied to the device.

This filter **180** has a generally conical configuration, tapering generally radially outwardly from its rearward end **182** to its forward end **184**. A length of the device adjacent its forward end is adapted to engage the walls of a lumen of a channel. The maximum diameter of the filter device **180** is therefore at least as large as the inner diameter of the channel in which it is to be positioned so that at least the forward end will engage the wall of the vessel to substantially lock the device in place.

Having a series of unsecured ends **185** of the wire strands adjacent the forward end of the device will assist in seating the device in the channel because the ends of the wires will tend to dig into the vessel wall slightly as the forward end of the device urges itself toward its fully expanded configuration within the vessel. The combination of the friction between the outwardly urging forward end of the device and the tendency of the wire ends to dig into the vessel walls will help ensure that the device remains in place where it is deployed rather than floating freely within a vessel to reach an undesired location.

The method in which the device **180** of the invention is deployed may vary depending on the nature of the physiological condition to be treated. For example, in treating an arterio-venous fistula, the device may be carefully positioned, as described above, to occlude the flow of blood at a fairly specific location. In treating other conditions (e.g. an arterio-venous malformation), however, it may be desired to simply release a number of these devices upstream of the malformation in a vessel having a larger lumen and simply allow the devices to drift from the treatment site to lodge in smaller vessels downstream.

The decision as to whether the device **180** should be precisely positioned at an exact location within the channel in a patient's body or whether it is more desirable to allow the device(s) to float to their final lodging site will depend on the size of the channels involved and the specific condition to be treated. This decision should be left to the individual operator to be made on a case-by-case basis as his

or her experience dictates; there is no one right or wrong way to deploy the device **180** without regard to the conditions at hand.

In the embodiment shown in FIGS. **9A** and **9B**, the wall of the device extends generally linearly from a position adjacent the clamp **90** and the other end of the device, approximating a conical shape. Due to the presence of the clamp **90**, though, the end of the device immediately adjacent the clamp may deviate slightly from the cone shape, as indicated in the drawings. Alternatively, the wall may be curved so that the diameter of the device changes more rapidly adjacent the rearward end than it does adjacent its forward end, having an appearance more like a rotation of a parabola about its major axis than a true cone. Either of these embodiments should suffice in occluding a vessel with the device **180**, such as to occlude a vessel.

The ends of the wire strands at the rearward end **182** of the device are secured with respect to one another, such as by means of a threaded clamp **90** such as that described above in connection with FIGS. **6A–6C**. Portions of the wire strands adjacent the forward end **184** may also be secured against relative movement, such as by spot welding wires to one another where they cross adjacent the forward end. Such a spot weld is schematically illustrated at **186** in FIGS. **9A** and **9B**.

In the embodiment illustrated in FIG. **9**, though, the ends of the wire strands adjacent the forward end **184** in the finished device need not be affixed to one another in any fashion. These strands are held in a fixed position during the forming process to prevent the metal fabric from unraveling before it is made into a finished device. While the ends of the wire strands adjacent the forward end remain fixed relative to one another, they can be heat treated, as outlined above. The heat treatment will tend to fix the shapes of the wires in their deformed configuration wherein the device generally conforms to a molding surface of the molding element. When the device is removed from contact with the molding element, the wires will retain their shape and tend to remain intertwined. Accordingly, when the device is released from contact with the molding element, even if the ends of the wires are released from any constraint the device should still substantially retain its shape.

FIGS. **10A–10C** illustrate three suitable molds for use in forming the filter **180** of FIGS. **9A** and **9B**. In FIG. **10A**, the molding element **200** is a single piece which defines a pair of generally conical portions abutting one another. In another similar embodiment (not shown), the molding element **200** may be generally ovoid, shaped not unlike an American football or a rugby ball. In the embodiment illustrated in FIG. **10A**, though, the molding element is a little bit less rounded. This molding element comprises two conical segments **202** which abut one another at their bases, defining a larger diameter at the middle **204** of the element which can taper relatively uniformly toward the ends **206** of the element **200**.

When the a tubular braid is used in forming this device, the tubular metal fabric may be applied to the molding element by placing the molding element within the tubular braid and clamping the ends of the braid about the molding element before cutting the braid to the desired length. In order to better facilitate the attachment of the clamps **90** to the ends of the tubular braid, the ends **206** of the molding element may be rounded, as shown, rather than tapering to a sharper point at the ends of the molding element. In order to ensure that the braid more closely conforms to the outer surface of the molding element **200**, i.e. the molding

element's molding surface, the natural, relaxed diameter of the braid should be less than the maximum diameter of the element, which occurs at its middle **204**. This will place the metal fabric in tension about the middle of the element and, in combination with the clamps at the ends of the braid, cause the braid to generally conform to the molding surface.

FIG. **10B** illustrates an alternative molding element **210** for forming a device substantially as shown in FIGS. **9A** and **9B**. Whereas the molding element **200** is intended to be received within a recess in the metal fabric, such as within the lumen of a length of tubular braid, the molding element **210** has an internal cavity **212** adapted to receive the fabric. In this embodiment, the molding element may comprise a pair of molding sections **214**, **216** and these mold sections may be substantially identical in shape. Each of the molding sections **214**, **216** generally comprise a conical inner surface **220** defined by a wall **222**. Each section also may be provided with a generally cylindrical axial recess **224** for receiving a clamp **15** (or **90**) carried by an end of the metal fabric.

The two molding sections should be readily attached to one another with the larger, open ends **226** of the sections abutting one another. The mold sections can simply be clamped together, such as by providing a reusable jig (not shown) which can be used to properly position the sections **214**, **216** with respect to one another. If so desired, bolt holes **228** or the like may be provided to allow a nut and bolt, or any similar attachment system, to be passed through the holes and attach the sections **214**, **216** together.

In use, a suitably sized piece of a metal fabric, optimally a length of a tubular braid, is placed in the recess **212** of the molding element and the two molding sections **214**, **216** are urged toward one another. The fabric should have a relaxed axial length longer than the axial length of the recess **212** so that bringing the sections toward one another will axially compress the fabric. This axial compression will tend to urge the wire strands of the braid radially outwardly away from the axis of the braid and toward engagement with the molding surface of the element **210**, which is defined by the surface of the recess **212**.

Once the metal fabric is deformed to generally conform to the molding surface of either molding element **200** or **210**, the fabric can be heat treated to substantially set the shape of the fabric in its deformed state. If molding element **200** is used, it can then be removed from the interior of the metal fabric. If there is sufficient room between the resilient wire strands, the molding element can simply be removed by opening the web of wire strands and pulling the molding element out of the interior of the metal fabric. If molding element **210** is employed, the two molding sections **214**, **216** can be moved away from one another and the molded fabric can be retrieved from the recess **212**. Depending on the shape of the molding surface, the resulting formed shape may resemble either a pair of abutting hollow cones or, as noted above, a football, with clamps, welds or the like provided at either end of the shape.

This shape can then be cut into two halves by cutting the wires in a direction generally perpendicular to the shared axis of the cones (or the major axis of the ovoid shape) at a location about midway along its length. This will produce two separate filter devices **180** substantially as illustrated in FIGS. **9A** and **9B**. If the wires strands are to be joined adjacent the forward end of the device (such as by the weldments shown as **186** in FIGS. **9A** and **9B**), this can be done before the conical or ovoid shape is severed into two halves. Much the same net shape could be accomplished by

cutting the metal fabric into halves while it is still carried about molding element **200**. The separate halves having the desired shape could then be pulled apart from one another, leaving the molding element ready for forming additional devices.

In an alternative embodiment of this method, the molding element **200** is formed of a material selected to permit the molding element to be destroyed for removal from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material, such as glass. Once the material has been heat treated in contact with the molding surface of the molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The glass shards can then be removed from the enclosure of the metal fabric. The resultant shape can be used in its generally conical shape, or it can be cut into two separate halves to produce a device substantially as shown in FIGS. **9A** and **9B**.

Alternatively, the molding element **200** can be formed of a material which can be chemically dissolved, or otherwise broken down, by a chemical agent which will not substantially adversely affect the properties of the metal wire strands. For example, the molding element can be formed of a temperature-resistant plastic resin which is capable of being dissolved with a suitable organic solvent. The fabric and the molding element can be subjected to a heat treatment to substantially set the shape of the fabric in conformance with the surface of the molding element, whereupon the molding element and the metal fabric can be immersed in the solvent. Once the molding element is substantially dissolved, the metal fabric can be removed and either used in its current shape or cut into separate halves, as outlined above.

Care should be taken to ensure that the material selected to form the molding element is capable of withstanding the heat treatment without losing its shape, at least until the shape of the fabric has been set. For example, the molding element could be formed of a material having a melting point above the temperature necessary to set the shape of the wire strands, but below the melting point of the metal forming the strands. The molding element and metal fabric can then be heat treated to set the shape of the metal fabric, whereupon the temperature can be increased to substantially completely melt the molding element, thereby removing the molding element from within the metal fabric.

It should be understood that the methods outlined immediately above for removing the metal fabric **10** from the molding element **200** can be used in connection with other shapes, as well. Although these methods may not be necessary or desirable if the molding element is carried about the exterior of the metal fabric (such as are elements **30-40** of the molding element **20** of FIGS. **2-4**), if the molding element or some portion thereof is enclosed within the formed metal fabric (such as the internal molding section of the molding element **20**), these methods can be used to effectively remove the molding element without adversely affecting the medical device being formed.

FIG. **10C** illustrates yet another molding element **230** which can be used in forming a medical device such as that illustrated in FIGS. **9A** and **9B**. This molding element comprises an outer molding section **232** defining a tapered inner surface **234** and an inner molding section **236** having an outer surface **238** substantially the same shape as the

tapered inner surface **234** of the outer molding section. The inner molding section **236** should be sized to be received within the outer molding section, with a piece of the metal fabric (not shown) being disposed between the inner and outer molding sections. The molding surface of this molding element **230**, to which the fabric will generally conform, can be considered to include both the inner surface **234** of the outer molding section and the outer surface **238** of the inner molding section.

This molding element **230** can be used with a metal fabric which is in the form of a tubular braid. If such a fabric is used and a clamp **15** (not shown in this drawing) or the like is provided to connect the ends of the wire strands adjacent one end of the device, a recess (not shown) analogous to the cavity **46** in the face of the compression disk **44** of molding element **20** (FIGS. **2-4**) can be provided for receiving the clamp.

However, the present molding element **230** can be used quite readily with a flat woven piece of metal fabric, such as is illustrated in FIG. **1B**. In using such a fabric, a suitably sized and shaped piece of fabric is cut; in using the molding element **230** to produce a device **180** analogous to that shown in FIGS. **9A** and **9B**, for example, a generally disk-shaped piece of the metal fabric **10'** can be used. The metal fabric is then placed between the two sections **232**, **236** of the molding element and the sections are moved together to deform the fabric therebetween. After heat treatment, the fabric can be removed and will retain substantially the same shape as it had when it was deformed between the two molding sections.

As can be seen by the discussion of the various molding elements **200**, **210** and **230** in FIGS. **10A-10C**, it should be clear that a number of different molding elements may achieve essentially the same desired shape. These molding elements may be received entirely within a closed segment of fabric and rely on tension and/or compression of the fabric to cause it to generally conform to the molding surface of the molding element, as with the element **200** of FIG. **10A**. The molding element **210** of FIG. **10B** substantially encloses the fabric within a recess in the mold and relies on compression of the fabric (in this case axial compression of a tubular braid) to deform the fabric to the desired configuration. Finally, the fabric may be compressed between two coacting parts of the molding element to deform the fabric, such as between the two sections **232**, **236** of molding element **230** in FIG. **10C**. Any one or more of these techniques may be used in achieving a finished product having a desired shape.

The method in accordance with the present invention further includes a method of treating a physiological condition of a patient. In accordance with this method, a medical device suitable for treating the condition, which may be substantially in accordance with one of the embodiments outlined above, is selected. For example, if a patent ductus arteriosus is to be treated, the PDA occlusion device **80** of FIGS. **6A-6C** can be selected. Once the appropriate medical device is selected, a catheter may be positioned within a channel in patient's body to place the distal end of the catheter adjacent the desired treatment site, such as immediately adjacent (or even within) the shunt of the PDA.

Medical devices made in accordance with the method of the invention outlined above have a preset expanded configuration and a collapsed configuration which allows the device to be passed through a catheter. The expanded configuration is generally defined by the shape of the medical fabric when it is deformed to generally conform to

the molding surface of the molding element. Heat treating the metal fabric substantially sets the shapes of the wire strands in the reoriented relative positions when the fabric conforms to the molding surface. When the metal fabric is then removed from the molding element, the fabric may define a medical device in its preset expanded configuration.

The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter. For example, the devices shown in FIG. 5 may have a relatively elongated collapsed configuration wherein the devices are stretched along their axes. This collapsed configuration can be achieved simply by stretching the device generally along its axis, e.g. by manually grasping the clamps 15 and pulling them apart, which will tend to collapse the expanded diameter portions 64 of the device 60 inwardly toward the device's axis. The PDA occlusion device 80 of FIG. 6 also operates in much the same fashion and can be collapsed into its collapsed configuration for insertion into the catheter by applying tension generally along the axis of the device. In this regard, these devices 60 and 80 are not unlike "Chinese handcuffs", which tend to constrict in diameter under axial tension.

Once the medical device is collapsed and inserted into the catheter, it may be urged along the lumen of the catheter toward the distal end of the catheter. This may be accomplished by using a guidewire or the like to abut against the device and urge it along the catheter. When the device begins to exit the distal end of the catheter, which is positioned adjacent the desired treatment site, it will tend to resiliently return substantially entirely to its preset expanded configuration. Superelastic alloys, such as nitinol, are particularly useful in this application because of their ability to readily return to a particular configuration after being elastically deformed to a great extent. Hence, simply urging the medical device out of the distal end of the catheter tend to properly deploy the device at the treatment site.

Although the device will tend to resiliently return to its initial expanded configuration (i.e. its shape prior to being collapsed for passage through the catheter), it should be understood that it may not always return entirely to that shape. For example, the device 60 of FIG. 5 is intended to have a maximum outer diameter in its expanded configuration at least as large as and preferably larger than, the inner diameter of the lumen in which it is to be deployed. If such a device is deployed in a vessel having a small lumen, the lumen will prevent the device from completely returning to its expanded configuration. Nonetheless, the device would be properly deployed because it would engage the inner wall of the lumen to seat the device therein, as detailed above.

If the device is to be used to permanently occlude a channel in the patient's body, such as the devices 60 and 80 described above may be, one can simply retract the catheter and remove it from the patient's body. This will leave the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means, such as when the threaded clamp 90 shown in FIGS. 6 and 9 are attached to a distal end of the delivery means, as explained above. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

While a preferred embodiment of the present invention has been described, it should be understood that various

changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A method of forming a medical device comprising the steps of:

- (a) providing a metal fabric formed of a plurality of strands, the strands being formed of a metal which can be heat treated to substantially set a desired shape;
- (b) deforming the metal fabric outwardly to generally conform to an internal surface of a molding element;
- (c) heat treating the metal fabric in contact with the internal surface of the molding element at an elevated temperature, the temperature and the duration of the heat treatment being sufficient to substantially set the shape of the fabric in its deformed state; and
- (d) removing the metal fabric from contact with the internal surface of the molding element, whereby the metal fabric defines a medical device which can be collapsed for passage through a catheter for deployment in a channel of the patient's body.

2. The method of claim 1 wherein the metal of which the strands are formed is a shape memory alloy, stainless steel, or elgiloy, the temperature and the duration of the heat treatment being selected to substantially set the strands in a deformed state.

3. The method of claim 2 wherein the metal of which the strands are formed comprises nitinol, the temperature of the heat treatment being between about 350° C. and about 900° C. and the duration of the heat treatment being between about thirty seconds and about one hour.

4. The method of claim 1 wherein the molding element comprises a plurality of mold sections, each mold section having an internal surface, the mold sections being assembled such that the internal surfaces of the mold sections together defining the internal surface of the molding element.

5. The method of claim 4 wherein the mold sections are assembled about the metal fabric to substantially enclose the fabric within the molding element.

6. A method of forming a medical device for deployment in a channel in a patient's body, the device having a pre-set expanded configuration and a collapsed configuration enabling passage of the device to a catheter, comprising the steps of:

- (a) providing a metal fabric formed of a plurality of strands having a first relative orientation with respect to one another, the strands being formed of a metal which can be heat treated to substantially set a desired shape;
- (b) generally conforming the metal fabric to an internal surface of a molding element to substantially define the device's expanded configuration, thereby reorienting the relative positions of the strands with respect to one another;
- (c) treating the metal fabric while conformed to the internal surface of the molding element to substantially set the strands in their reoriented relative positions; and
- (d) removing the metal fabric from contact with the internal surface of the molding element, whereby the metal fabric defines a medical device which can be deformed into its collapsed configuration for passage through a catheter for deployment in a channel of a patient's body, and which substantially resumes its pre-set expanded configuration in such channel.

7. The method of claim 6 wherein the molding element comprises a plurality of mold sections, each mold section

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having an internal surface, the mold sections being assembled such that the internal surfaces of the mold sections together defining the internal surface of the molding element.

8. The method of claim 7 wherein the mold sections are assembled about the metal fabric to substantially enclose the fabric within the molding element.

9. A method of forming and using a medical device comprising the steps of:

- (a) providing a tubular fabric braid formed of a plurality of strands, the strands being formed of a material which can be heat treated to substantially set a desired shape;
- (b) axially compressing the tubular braid to urge the fabric outwardly to generally conform to an internal surface of a molding element;
- (c) heat treating the tubular braid in contact with the internal surface of the molding element at an elevated temperature, the temperature and the duration of the heat treatment being sufficient to substantially set the shape of the tubular braid in its deformed state; and
- (d) removing the tubular braid from contact with the internal surface of the molding element, whereby the fabric defines a medical device which can be collapsed for passage through a catheter for deployment in a channel of a patient's body.

10. The method of claim 9 wherein the molding element comprises a plurality of mold sections, each mold section having an internal surface, the mold sections being assembled such that the internal surfaces of the mold sections together defining the internal surface of the molding element.

11. The method of claim 10 wherein the mold sections are assembled about the metal fabric to substantially enclose the fabric within the molding element.

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12. The method of claim 10 wherein the molding element further comprises an internal mold section, the internal mold section being placed within the tubular braid.

13. The method of claim 9 wherein the molding element comprises a plurality of mold parts, the mold parts being assembled to define a molding element having a pair of enlarged diameter cavities on opposite sides of a center section having a reduced diameter port therethrough, internal surfaces of the cavities and the reduced diameter port together defining the internal surface of the molding element.

14. The method of claim 13 wherein the molding element further comprises an internal mold section, the internal mold section being placed within the tubular braid such that it will be disposed within the reduced diameter port when the mold parts are assembled.

15. The method of claim 13 wherein the tubular braid has a relaxed diameter prior to the heat treatment, the relaxed diameter being greater than an internal diameter of the reduced diameter port.

16. The method of claim 9 wherein the molding element comprises at least one cavity for receiving an end of the tubular braid, the method comprising inserting an end of the braid in said cavity.

17. The method of claim 9 further comprising collapsing the medical device, urging the collapsed medical device through a channel in a patient's body to a treatment site, and permitting the collapsed medical device to resiliently substantially return to its initial, uncollapsed configuration at the treatment site.

\* \* \* \* \*

**EXHIBIT B**



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## INVESTOR INFORMATION

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NMT Medical – Bringing closure to cardiac sources of stroke

NMT Medical, Inc. is a publicly traded company (Nasdaq symbol NMTI), based in Boston, Massachusetts, that designs, develops, and markets innovative medical devices for the minimally invasive (non-surgical) treatment of patients who have cardiac sources of embolic stroke.

Worldwide, approximately 500,000 people every year suffer an embolic stroke due to a condition called patent foramen ovale (PFO). It is estimated that PFO occurs in approximately 25% of the population. NMT's PFO closure products are designed to treat patients who have experienced PFO-induced stroke and live in fear of another.

The traditional therapy for embolic stroke is lifelong anticoagulation drug regimens. These regimens impose significant lifestyle restrictions on patients, often have side effects and rely heavily on individual patient compliance - which is not practical or achievable in all cases. Should the regimen not be effective, a further stroke could occur at any time. The societal costs of stroke disability are well documented - the personal costs immeasurable.

With NMT's products, non-surgical, catheter-based closure of the PFO can usually be achieved in less than an hour. This therapy offers peace of mind for the patient and lasts a lifetime.

NMT recently embarked on a 1600 patient randomized, controlled clinical trial, called **CLOSURE I**, designed to evaluate the effectiveness of transcatheter PFO closure using the company's proprietary **STARFlex®** cardiac septal repair implant compared to best medical therapy.

NMT Medical was the first company to gain regulatory approvals in the United States and Europe for devices to be used for the non-surgical closure of the PFO. Our leadership in PFO closure is further demonstrated by the length of our experience and the number of implants in this application. More than 13,000 PFO procedures have been performed worldwide.

### Clinical Trials:



PFO Stroke Connectio



Migraine Study

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[www.operationstrokenov.com](http://www.operationstrokenov.com)

Please contact us via email at:  
[investorrelations@nmtmedical.com](mailto:investorrelations@nmtmedical.com)

STARFlex® and CardioSEAL® are both commercially available in Europe. CardioSEAL is available under HDE (humanitarian device exemption) in the USA. STARFlex is an investigational device in the US and is only available to patients in the CLOSURE I PFO, stroke and TIA clinical trial. See the [FDA disclaimer page](#) for more information.



**Title**

NMT Medical Conference Call to Update Investors on Developments Related to Its Migraine Study

**Date and Time**

Friday, January 7, 2005 10:30 a.m. ET

---

## NMT Medical

BRINGING CLOSURE TO  
CARDIAC SOURCES OF STROKE™  
[info@nmtmedical.com](mailto:info@nmtmedical.com)

[investor relations](#) | [products](#) | [clinical applications](#) | [jobs](#)

**EXHIBIT C**



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## CARDIAC IMPLANTS

### >) Atrial Septal Defect

[What is an ASD?](#)

[Effect of ASD on the body](#)

[Treatment via surgery](#)

[Risks and complications of surgery](#)

**How CardioSEAL and STARFlex close ASD's**

[Advantages of CardioSEAL and STARFlex over surgery](#)

[Risks and complications of implants](#)

CardioSEAL® and STARFlex™ are constructed of a metal framework shaped like an umbrella to which a polyester fabric is securely attached. The only difference between CardioSEAL and STARFlex is that STARFlex has incorporated a centering system made of a fine wire microspring.

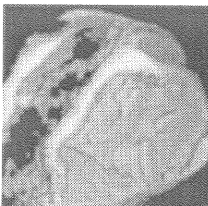
Both Occluders are comprised of two of these umbrellas, one for each side of the septum. Both the metal and fabric are made from some of the most biocompatible materials known for this application. The framework in particular has been selected for its excellent biocompatibility profile. After all, this implant will be in the patient for the life of the patient.

Using spring coils in the framework, the Occluders can be collapsed into a very small tube for insertion into the heart. Once inserted through the tube, the Occluder is opened, with an umbrella positioned on each side of the defect. The spring coil design gives the Occluders two unique features:

1. It holds the Occluder in place at the site of the defect.
2. It allows the device to conform to variations in the anatomy of the septum, keeping a low profile on the septum without bulging out into the flow of blood through the atria or imposing on other heart structures.

With STARFlex, the centering microsprings cause the device to center itself in the defect independent of the shape of the defect, without distorting the surrounding heart structures.

Once in position, the Occluder is released from the catheter, and tissue grows into and around the umbrella, incorporating it into the native septum.



[ATRIAL SEPTAL DEFECT \(ASD\)](#)

[VENTRICULAR SEPTAL DEFECT](#)

[PATENT FORAMEN OVALE \(PFO\) IN STROKE PATIENTS](#)

[IMPORTANT CONSIDERATIONS](#)

[WHERE IS CardioSEAL & STARFlex AVAILABLE](#)

[MORE ABOUT CardioSEAL](#)

[MORE ABOUT STARFlex](#)

[CLINICAL RESULTS WITH STARFlex](#)

[FIND A CardioSEAL TRAINED PHYSICIAN](#)

[VIDEOS, PRESENTATIONS, ANIMATIONS, ETC.](#)

[FDA DISCLAIMER](#)

3-D reconstruction of CardioSEAL in place.  
(courtesy Lee Benson, MD)

**EXHIBIT D**



INVESTOR  
RELATIONS

PRODUCTS

CLINICAL  
APPLICATIONS

JOB  
OPPORTUNITIES

home | search | legal | ne

## CARDIAC IMPLANTS

### >) ASD Clinical Trial Locations

#### ASD clinical trial locations

#### PFO clinical trial locations

#### High Risk clinical trial locations



James Lock, MD (Kathy Jenkins, MD)  
Children's Hospital - Boston  
Boston, MA 02115  
Phone: 617 355 7313

Charles Mullins, MD  
Texas Children's Hospital  
Houston, TX 77030  
Phone: 713 770 5901

William Hellenbrand, MD  
Yale-New Haven Hospital  
New Haven, CT 06510  
Phone: 203 785 2022

Larry Latson, MD  
Cleveland Clinic Foundation  
Cleveland, OH 44195  
Phone: 216 445 6532

Phillip Moore, MD  
UCSF-Stanford Health Care  
San Francisco, CA 94143  
Phone: 415 476 8488

Jonathan Rome, MD  
Children's Hospital of Philadelphia  
Philadelphia, PA 19104  
Phone: 215 590 1790

ATRIAL SEPTAL DEFECT (ASD)

VENTRICULAR SEPTAL DEFECT (VSD)

PATENT FORAMEN OVALE (PFO)  
IN STROKE PATIENTS

IMPORTANT CONSIDERATIONS

WHERE IS CardioSEAL & STARFlex  
AVAILABLE

MORE ABOUT CardioSEAL

MORE ABOUT STARFlex

CLINICAL RESULTS WITH STARFlex

FIND A CardioSEAL TRAINED  
PHYSICIAN

VIDEOS, PRESENTATIONS  
ANIMATIONS, ETC.

FDA DISCLAIMER

Evan M. Zahn, MD  
Miami Children's Hospital  
Miami, FL 33155-4075  
Phone: 305 662 8301

William Berman, Jr., MD  
Presbyterian Hospital  
Albuquerque, NM 87102  
Phone: 505-848-3700

Marc Boucek, MD  
Denver Children's Hospital  
Denver, CO 80218-1088  
Phone: 303-837-2932

Garth Orsmond, MD  
Primary Children's Medical Center  
Salt Lake City, UT 84113  
Phone: 801-588-2600

Abraham Rothman, MD  
Chief, Division of Pediatric Cardiology  
U. of California, San Diego  
San Diego, CA 92103  
Phone: 619 543 2927

Ray Matthews, MD, PhD.  
Department of Cardiology  
Good Samaritan Hospital  
Los Angeles, CA 90017  
Phone: (909) 824-4652

Frank Cetta, Jr., MD  
Pediatric Cardiology  
Loyola University Medical Center  
Maywood, IL 60153  
(708) 327-9102

Allison Cabalka, MD  
Childrens Heart Clinic  
Abbott Northwestern Hospital  
Minneapolis, MN 55404  
(612) 871-4660

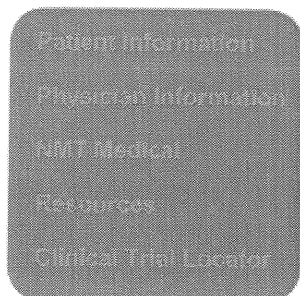
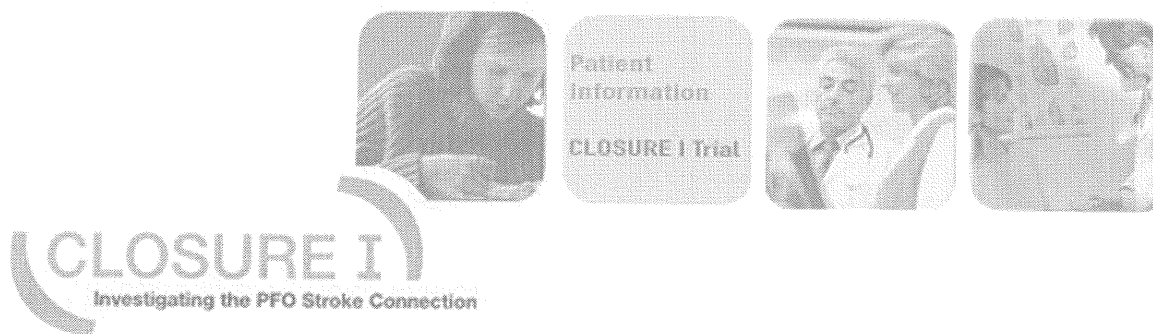
Grant Burch, MD  
University of Oregon Health Sciences Center  
Portland, OR 97201  
Phone: 503 494 2192

Canadian Site:

Lee Benson, MD  
Hospital for Sick Children  
Toronto, ON Canada M5G 1X8

Phone: 416-813-6141

**EXHIBIT E**



There was 1 site found in St. Paul. Perform a new search.



### United's John Nasseff Heart Hospital

[www.unitedhospital.com/ahs/united.nsf](http://www.unitedhospital.com/ahs/united.nsf)  
St. Paul, MN 55102

#### Contact

##### Neurology Principal Investigator:

John Floberg, MD (651) 291-1559 (phone)

##### Cardiology Principal Investigator:

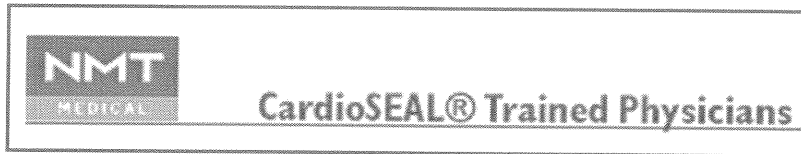
Kenneth Baran, MD (651) 292-0616 (phone)

##### Study Coordinator:

Teri Walsh, RT(R), CCRC (651) 241-8535 (phone)  
(612) 654-6177 (pager)  
[teri.walsh@allina.com](mailto:teri.walsh@allina.com)

Perform a new search.

**EXHIBIT F**



Last Name: **Baker**  
 First Name: **Charles**  
 Hospital/Dept.: Children's Hospital Minneapolis  
 Practice Name/Dept.: Children's Heart Clinic  
 Address: 2545 Chicago Avenue South, 3316  
 City: Minneapolis  
 State: MN  
 Zip: 55404  
 Phone: 612-813-8800  
**Map it**

---

Last Name: **Baran**  
 First Name: **Kenneth**  
 Hospital/Dept.: United John Nasseff Heart Hospital  
 Practice Name/Dept.: 255 North Smith Avenue, Ste. 100  
 Address:  
 City: St. Paul  
 State: MN  
 Zip: 55102  
 Phone: 651-292-0616  
**Map it**

---

Last Name: **Cabalka**  
 First Name: **Allison**  
 Hospital/Dept.: Mayo Clinic  
 Practice Name/Dept.: Cardiology Department  
 Address: 200 First Street  
 City: Rochester  
 State: MN  
 Zip: 55905  
 Phone: 507-266-0676  
**Map it**

---

Last Name: **Chambers**  
 First Name: **Jeffrey**  
 Hospital/Dept.: Mercy Hospital  
 Practice Name/Dept.: Metropolitan Cardiology Consultants  
 Address: 4040 Coon Rapids Blvd., Suite 120  
 City: Minneapolis  
 State: MN  
 Zip: 55433  
 Phone: 763-427-9980  
**Map it**

---

Last Name: **Holmes, Jr.**  
 First Name: **David**  
 Hospital/Dept.: Mayo Clinic  
 Practice Name/Dept.: Cardiology Department  
 Address: 200 First Street, SW  
 City: Rochester  
 State: MN  
 Zip: 55905

Phone: 507-255-2504  
[Map it](#)

---

Last Name: **Mooney**  
First Name: **Michael**  
Hospital/Dept.: Director, Interventional Cardiology  
Practice Name/Dept.: Abbott Northwestern Hospital  
Address: 800 East 28th Street  
City: Minneapolis  
State: MN  
Zip: 55407  
Phone: 612-863-3900  
[Map it](#)

---

Last Name: **Stark**  
First Name: **Randall**  
Hospital/Dept.: Mercy Hospital  
Practice Name/Dept.: Metropolitan Cardiology  
Address: 4040 Coon Rapids Blvd.  
City: Minneapolis  
State: MN  
Zip: 55433  
Phone: 763-427-9980  
[Map it](#)

---

[New search](#)

**EXHIBIT G**

ATYADM, PATENT

**U.S. District Court**  
**District of Minnesota (DMN)**  
**CIVIL DOCKET FOR CASE #: 0:04-cv-04200-JNE-JGL**

NMT Medical, Inc. et al v. Cardia, Inc.  
Assigned to: Judge Joan N Ericksen  
Referred to: Chief Mag. Judge Jonathan G Lebedoff  
Cause: 35:271 Patent Infringement

Date Filed: 09/22/2004  
Jury Demand: Defendant  
Nature of Suit: 830 Patent  
Jurisdiction: Federal Question

**Plaintiff****NMT Medical, Inc.**

represented by **Douglas-NA J Kline**  
Not Admitted  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**John B Gordon**  
Faegre & Benson - Mpls  
90 S 7th St Ste 2200  
Mpls, MN 55402-3901  
612-766-7000  
Fax: 6127661600  
Email: jgordon@faegre.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Kenneth-NA E Radcliffe**  
Not Admitted  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Rachel F Bond**  
Faegre & Benson - Mpls  
90 S 7th St Ste 2200  
Mpls, MN 55402-3901  
612-766-7000  
Fax: 612-766-1600  
Email: rbond@faegre.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**William-NA A Meunier**  
Not Admitted  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**Children's Medical Center  
Corporation**

represented by **Douglas-NA J Kline**  
(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**John B Gordon**  
(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Kenneth-NA E Radcliffe**  
(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Rachel F Bond**  
(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**William-NA A Meunier**  
(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Cardia, Inc.**

**Counter Claimant**

**Cardia, Inc.**

represented by **David A Allgeyer**  
Lindquist & Venum PLLP  
80 S 8th St Ste 4200  
Mpls, MN 55402  
612-371-3211  
Fax: 6123713207  
Email: dallgeyer@lindquist.com  
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**NMT Medical, Inc.**

represented by **Rachel F Bond**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Children's Medical Center**

represented by **Rachel F Bond**

**Corporation**

(See above for address)

**ATTORNEY TO BE NOTICED**

<b>Date Filed</b>	<b>#</b>	<b>Docket Text</b>
09/22/2004	<u>1</u>	COMPLAINT with jury demand against Cardia, Inc. (Filing fee \$ 150.) , filed by Children's Medical Center Corporation, NMT Medical, Inc. Assigned to Judge Joan N. Ericksen per patent list and referred to Magistrate Jonathan G. Lebedoff. Receipt No. 432768. 4:04AD616 (Attachments: # <u>1</u> Civil Cover Sheet # <u>2</u> Exhibit)(JMM) (Entered: 09/23/2004)
09/22/2004		Summons Issued as to Cardia, Inc. (JMM) (Entered: 09/23/2004)
09/22/2004	<u>2</u>	RULE 7.1 DISCLOSURE STATEMENT of NMT Medical, Inc. and Children's Medical Center Co. (JMM) (Entered: 09/23/2004)
09/24/2004	<u>3</u>	*DOCUMENT FILED IN ERROR; INCORRECT EVENT CODE* Return of Service Executed for Summons and Complaint served on Cardia, Inc. on 9/23/04, filed by Children's Medical Center Corporation, NMT Medical, Inc. (Bond, Rachel) Modified text on 9/28/2004 (HLL). (Entered: 09/24/2004)
09/24/2004	<u>4</u>	*DOCUMENT FILED IN ERROR; INCORRECT EVENT CODE USED* AFFIDAVIT of Service by Children's Medical Center Corporation, NMT Medical, Inc. re <u>2</u> Rule 7.1 - Disclosure Statement and Civil Cover Sheet (Bond, Rachel) Modified text on 9/28/2004 (HLL). (Entered: 09/24/2004)
09/28/2004	<u>5</u>	SUMMONS Returned Executed by Children's Medical Center Corporation, NMT Medical, Inc.. Cardia, Inc. served on 9/23/2004, answer due 10/13/2004. (Bond, Rachel) (Entered: 09/28/2004)
10/12/2004	<u>6</u>	ANSWER to Complaint with Jury Demand, COUNTERCLAIM against all plaintiffs by Cardia, Inc..(Allgeyer, David) (Entered: 10/12/2004)
10/12/2004	<u>7</u>	DISCLOSURES of Corporate Affiliations (Rule 7.1) by Cardia, Inc.. (Allgeyer, David) (Entered: 10/12/2004)
10/12/2004	<u>8</u>	CERTIFICATE OF SERVICE by Cardia, Inc. re <u>6</u> Answer to Complaint, Counterclaim, <u>7</u> Disclosures of Corporate Affiliations (Rule 7.1) (Allgeyer, David) (Entered: 10/12/2004)
10/13/2004	<u>9</u>	AFFIDAVIT of Service by Cardia, Inc. re <u>6</u> Answer to Complaint, Counterclaim, <u>7</u> Disclosures, <u>8</u> Certificate of Service on <i>Tester, Hurwitz &amp; Thibault, LLP</i> (Allgeyer, David) (Entered: 10/13/2004)
10/14/2004	<u>10</u>	NOTICE of Hearing: Pretrial Conference set for 11/22/2004 09:00 AM in Minneapolis - Courtroom 9E before Chief Mag. Judge Jonathan G Lebedoff. (Attachments: # <u>1</u> Consent Form)(SEA) (Entered: 10/14/2004)
10/27/2004	<u>11</u>	LETTER TO MAGISTRATE JUDGE by Children's Medical Center Corporation, NMT Medical, Inc.. (Gordon, John) (Entered: 10/27/2004)

11/01/2004	<u>12</u>	ANSWER to Counterclaim by NMT Medical, Inc., Children's Medical Center Corporation. (Attachments: # <u>1</u> Certificate of Service)(Bond, Rachel) (Entered: 11/01/2004)
11/15/2004	<u>13</u>	REPORT of Rule 26(f) Planning Meeting by Cardia, Inc., NMT Medical, Inc., Children's Medical Center Corporation.(Bond, Rachel) (Entered: 11/15/2004)
11/23/2004	<u>14</u>	PRETRIAL ORDER: Amended Pleadings due by 3/1/2005. Discovery due by 10/3/2005. Motions (non-disp) due 11/1/2005. Motions (disp) due by 12/1/2005. Ready for trial due by 3/1/2006.Signed by Chief Magistrate Judge Jonathan G Lebedoff on 11/23/04. (RJL) (Entered: 11/23/2004)
11/23/2004	<u>15</u>	NOTICE OF Settlement Conference set for 3/16/2005 09:00 AM in Minneapolis - Chambers 9E before Chief Mag. Judge Jonathan G Lebedoff. Signed by Chief Magistrate Judge Jonathan G Lebedoff on 11/23/04. (RJL) (Entered: 11/23/2004)
02/07/2005	<u>16</u>	STIPULATION <i>FOR PROTECTIVE ORDER</i> by Cardia, Inc., NMT Medical, Inc., Children's Medical Center Corporation. (Allgeyer, David) (Entered: 02/07/2005)

PACER Service Center			
Transaction Receipt			
02/07/2005 18:43:03			
<b>PACER Login:</b>	nm0073	<b>Client Code:</b>	aga
<b>Description:</b>	Docket Report	<b>Search Criteria:</b>	0:04-cv-04200-JNE-JGL
<b>Billable Pages:</b>	2	<b>Cost:</b>	0.16

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

---

NMT Medical, Inc., and Children's Medical  
Center Corporation,

**Civil No. 04-4200JNE/JGL**

Plaintiffs,

**COMPLAINT AND JURY DEMAND**

vs.

Cardia, Inc.,

Defendant.

---

Plaintiffs NMT Medical, Inc. (“NMT”), and Children’s Medical Center Corporation (“CMCC”), (collectively, “Plaintiffs”), file this Complaint for patent infringement against Cardia, Inc. (“Cardia”). As a result of such patent infringement, Plaintiffs have been damaged and irrevocably harmed, and seek injunctive relief, compensatory and multiple damages, attorneys’ fees, and costs and expenses.

**PARTIES**

1. NMT is a corporation organized and existing under the laws of the state of Delaware, and having a usual place of business in Boston, Massachusetts.

2. CMCC is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, and having a usual place of business in Boston, Massachusetts.

3. On information and belief, Cardia is a corporation organized and existing under the laws of the state of Minnesota, and maintains a regular place of business in Burnsville, Minnesota.

**JURISDICTION AND VENUE**

4. This action arises under the patent laws of the United States, including 35 U.S.C. § 271. This Court has exclusive jurisdiction over the subject matter of this action under 28 U.S.C. § 1338(a).

5. Venue is proper in the United States District Court for the District of Minnesota pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**COUNT I**

**INFRINGEMENT OF U.S. PATENT 5,451,235**

6. Plaintiffs re-allege and adopt by reference the allegations set forth in paragraphs 1-5 above.

7. On September 19, 1995 the United States Patent and Trademark Office duly and legally issued to Lock et al. United States Patent No. 5,451,235, entitled: OCCLUDER AND METHOD FOR REPAIR OF CARDIAC AND VASCULAR DEFECTS (the “‘235 patent”), a true and correct copy of which is attached hereto as Exhibit A.

8. CMCC is the assignee and owner of the ‘235 patent.

9. NMT is an exclusive licensee under the ‘235 patent.

10. On information and belief, Cardia has infringed and is infringing the ‘235 patent in the United States. On information and belief, Cardia’s acts of infringement include making, selling, and/or offering to sell closure devices, including its PFO Closure Devices, that fall within the scope of one or more claims of the ‘235 patent.

11. On information and belief, Cardia is making, selling, and/or offering for sale the infringing closure devices in this judicial district.

12. Cardia has notice of the '235 patent.
13. Cardia's infringement of the '235 patent has been willful.
14. Plaintiffs are without an adequate remedy at law because Cardia's infringement has irreparably harmed Plaintiffs and will continue to do so unless Cardia is enjoined by the Court from the actions complained of herein.

### **PRAYERS FOR RELIEF**

WHEREFORE, Plaintiffs pray for a judgment in their favor, including:

1. A finding that Cardia has infringed and continues to infringe the '235 patent;
2. A finding that Cardia's infringement of the '235 patent has been willful;
3. A preliminary and permanent injunction prohibiting Cardia, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with it, from further infringing the '235 patent throughout the patent's remaining enforceable term;
4. An award of Plaintiffs' damages proximately caused by Cardia's unlawful acts;
5. An award of increased damages and punitive damages for the willful nature of Cardia's unlawful acts, said award to equal at least three times the amount of Plaintiffs' actual damages;
6. An award of the costs and attorneys' fees Plaintiffs have incurred in bringing and maintaining this action;
7. An award of pre-judgment and post-judgment interest; and
8. Such other and further relief as the Court deems proper.

**Jury Trial Requested**

Plaintiffs request a trial by jury on all issues so triable.

Dated: September 22, 2004

FAEGRE & BENSON LLP

s/ John B. Gordon

John B. Gordon (#36237)

Rachel F. Bond (#325612)

2200 Wells Fargo Center

90 South Seventh Street

Minneapolis, MN 55402

Phone: (612) 766-7000 Fax: (612) 766-1600

*Of Counsel:*

Douglas J. Kline

William A. Meunier

Kenneth E. Radcliffe

TESTA, HURWITZ & THIBEAULT, LLP

125 High Street

Boston, MA 02110

Phone: (617) 248-7000 Fax: (617) 248-7100

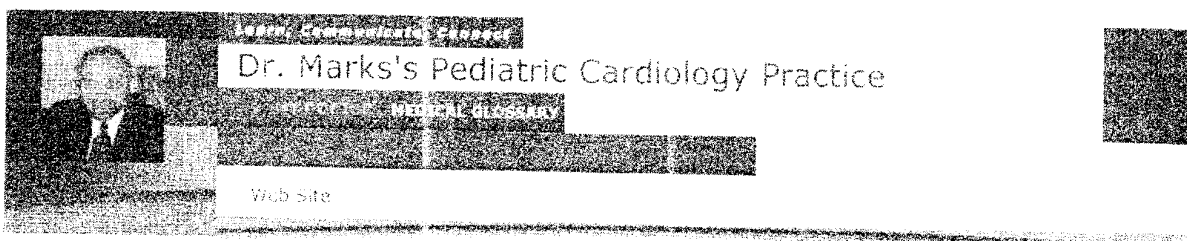
*Attorneys for Plaintiffs NMT Medical, Inc., and  
Children's Medical Center Corporation*

M2:20657589.01

**EXHIBIT H**

Home Page

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► Dr L. Marks: **Home Page**

## Home Page

**GO**

Dr L. Marks  
Home Page  
Locations Page  
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Procedure  
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Insurance  
Curriculum  
Vitae  
Dr. Marks'  
Practice  
Hospital  
Affiliations

### Dr. Marks' Practice ►

Dr. Lloyd Marks is a Board certified Pediatric Cardiologist in Northern New Jersey, serving Union County, Middlesex County, Essex County and Hudson County. His practice is restricted to pediatric cardiology, fetal cardiology, and adult congenital cardiology; Dr. Marks performs all tests personally including echocardiograms and cardiac catheterizations. He feels that his job is not complete unless you have an complete understanding of your (your child's) problem.

### Locations ►

#### Westfield Office [See map](#)

940 South Ave  
Suite A  
Westfield, New Jersey 07090  
908-789-0512  
908-789-0232 (FAX)

#### Belleville Office [See map](#)

36 Newark Avenue  
Suite 220  
Belleville, New Jersey 07110  
973-844-9700  
908-789-0232 (FAX)

#### Edison Office [See map](#)

98 James Street  
Suite 209  
Edison, New Jersey 08820  
732-632-9499  
908-789-0232 (FAX)

#### Bayonne Office [See map](#)

834 Avenue C  
Bayonne, New Jersey 07002  
(201) 222-1982  
(908) 789-0232 (FAX)

### Specialties ►

Patient Login

User ID

Password

☐ Accept Privacy Policy

**GO**

[New Patient?](#)

[Forgot Password?](#)

Medical News

\* No news available.

Home Page

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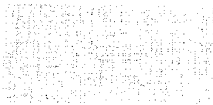
Pediatric Cardiology and Adult Congenital Cardiology

**Insurance**

Dr. Marks is a pediatric cardiologist in northern New Jersey who participate in many plans. See the list and call if your plan is not on the list. All patients are accepted for care.

**Patient Education Resources**

- [Heart Murmur](#) / AAP
- [Medical Conditions Affecting Sports Participation](#) / AAP
- [Infective Endocarditis](#) / NIH
- [Cardiac Dysrhythmias and Sports](#) / AAP




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Specialties

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## Dr. Marks's Pediatric Cardiology Practice

Web Site

Dr L. Marks: **Specialties**

**Specialties**

**Clinical Evaluation**

**Diagnostic Cardiac Catheterization**  
Small tubes are positioned in the heart to sample blood, measure pressures and to inject contrast agents to obtain angiograms (motion picture x-rays) of the heart.

**Echocardiography**  
Ultrasound Examination of the Heart

**Interventional Catheterization**  
Therapeutic procedures performed during a catheterization that result in a desired change in the heart or blood vessels. Examples include opening obstructed valves or vessels or closing unwanted holes or vessels.

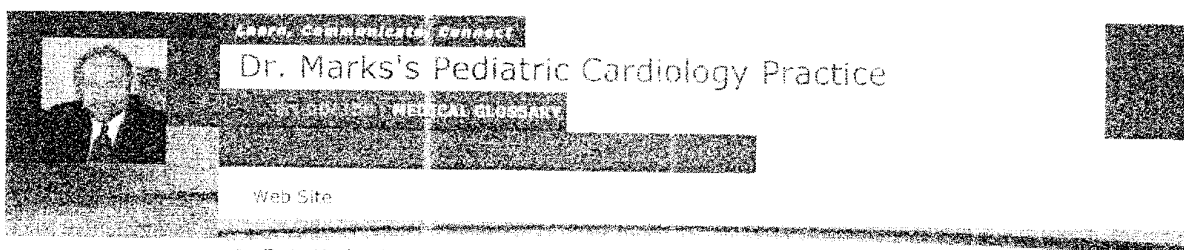
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Insurance

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Dr L. Marks: **Insurance**

### Insurance Information

	Plan Name	Accepting new patients?
	Please call for full listing	Yes
Dr L. Marks	Aetna/US Healthcare	Yes
Home Page	Americaid	Yes
Locations Page	Americare	Yes
Specialties	Amerihealth	Yes
Procedure	Beech Street	Yes
Page	Blair Mill	Yes
Insurance	Blue Choice	Yes
Curriculum	BC/BS of NJ	Yes
Vitae	Blue Select	Yes
Dr. Marks' Practice	CAPP Care	Yes
Hospital	CHIP	Yes
Affiliations	CHIP	Yes
	CIGNA	Yes
	CHN	Yes
	Empire BC/BS	Yes
	Ethix	Yes
	Erisa Exempt	Yes
	First Option	Yes
	First Health	Yes
	GHI	Yes
	Guardian	Yes
	Health Plans of America NJ	Yes
	Heritage	Yes
	Horizon	Yes
	HMO Blue	Yes
	Keystone	Yes
	Liberty	Yes
	Magnacare	Yes
	Managed Healthcare Systems	Yes
	Americhoice	Yes
	Mastercare	Yes
	Medicaid	Yes
	Medicare	Yes
	Medichoice	Yes
	Mercy	Yes
	Mission	Yes
	Multiplan	Yes
	National Advantage	Yes
	NJ Car	Yes
	Nylcare	Yes
	Oxford	Yes

Insurance

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PHS	Yes
Pro-Net	Yes
Prudential	Yes
United Healthcare	Yes
Qualicare	Yes
United Payors & Providers	Yes
University Health Plan	Yes

**Hospital Affiliations**

JFK Medical Center, Edison, NJ

Bayonne Hospital, Bayonne, NJ

Muhlenberg Regional Medical Center, Plainfield, NJ

Clara Maass Hospital, Belleville, NJ

Clara Maass Hospital, Belleville, NJ

Columbus Hospital, Newark, NJ

Christ Hospital, Jersey City, NJ

Deborak Heart & Lung Center, Browns Mills, NJ

Elizabeth General, Elizabeth, NJ

St. Elizabeth's, Elizabeth, NJ

Jersey City Medical Medical Center, Jersey City, NJ

Mountainside Hospital, Montclair, NJ

Mt. Sinai Medical Center, New York, NY

Newark Beth Israel, Newark, NJ

Overlook Hospital, Summit, NJ

Raritan Bay Medical Center, Perth Amboy, NJ

Robert Wood Johnson, New Brunswick, NJ

St. Barnabas Medical Center, Livingston, NJ

St. Mary Hospital, Hoboken, NJ

St. Christopher's Hosp for Children, Phila, PA

St. Joseph's Children's Hospital, Paterson, NJ

UMDNJ, Newark, NJ

Insurance

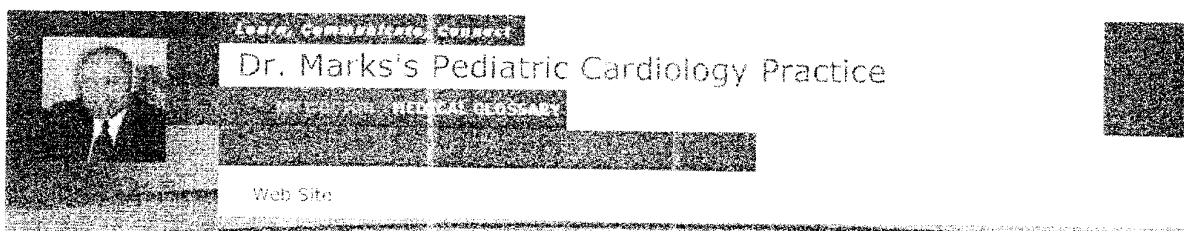
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► Dr. L. Marks: Curriculum Vitae

## Curriculum Vitae

**Date Of Birth**  
10/22/1950

**Place Of Birth**  
Brooklyn, NY

**Work Address**  
940 South Avenue  
Westfield, NJ 08090

**Education**  
1967-1971, B.S. Electrical Engineering. Massachusetts Institute of Technology  
1972 - 1976, M.D., University of Michigan Medical School

**Post Doctoral Training**  
Pediatrics Internship, UC San Diego, 1976-77  
Pediatrics Residency, Children's National Medical Center, Wash, DC, 1978-79  
Pediatric Cardiology Fellowship, Johns Hopkins University, Baltimore, MD, 1980-1983

**Research Fellowships**  
National Institutes of Health, 1977-1978

**Licensure and Board Certification**  
Diplomate, American Board of Pediatrics (#24583)  
Diplomate, Sub-Board of Pediatric Cardiology (#0744)  
New York State Medical License (#155825)  
Pennsylvania State Medical License (#MD-036389-E)  
New Jersey State Medical License (#61495)

**Academic & Administrative Appointments**  
Associate Professor of Pediatrics, UMDNJ  
Adjunct Associate Professor of Pediatrics, Mt. Sinai School of Medicine

**Memberships, Offices and Committee Appointments**  
Fellow of the American College of Cardiology (ACC)

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Curriculum  
Vitae  
Dr. Marks'  
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Affiliations

**Other Professional Positions & Major Appointments**

Director of Cardiovascular Laboratory, St. Christopher's Hospital for Children, 1986-1994

Chief of Pediatric Cardiology, The Children's Hospital of New Jersey, 1994-1997

**Editorial Boards**

Biomedical Instrumentation and Technology 1993-2000

Cardiovascular Engineering 2000-Current

**Research Interests**

Biomedical Engineering

Patient Monitoring

Interventional Cardiology

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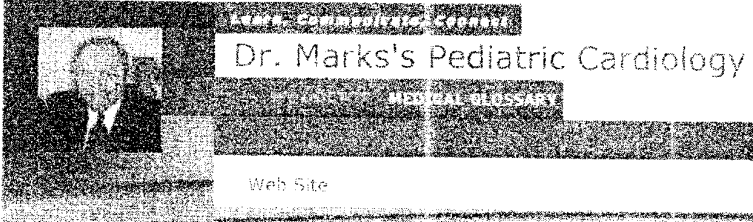
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Dr. [Name] is a board certified pediatric cardiologist and a board member of the American Heart Association. He is currently a professor of Pediatrics and a member of the faculty of the [Institution]. He has been in practice since 1980 and has been a member of the American Heart Association since 1985. He is currently a member of the American College of Cardiology and the American Society of Echocardiography. He has been a member of the American Heart Association since 1985. He is currently a member of the American College of Cardiology and the American Society of Echocardiography.

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Dr. Marks' Practice

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► Dr L. Marks: **Dr. Marks' Practice**


## Dr. Marks' Practice

Dr. Lloyd Marks is a Board certified Pediatric Cardiologist in Northern New Jersey, serving Union County, Middlesex County, Essex County and Hudson County. His practice is restricted to pediatric cardiology, fetal cardiology, and adult congenital cardiology; He performs outpatient & inpatient evaluations, echocardiography, fetal echocardiography, stress tests, holter monitoring, arrhythmia management, cardiac catheterization & interventional cardiology procedures (including balloons, coils, and stents. Office locations are in Westfield, Edison, Belleville and Bayonne.

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**EXHIBIT I**



US005108420A

## United States Patent [19]

(ii) Patent Number: 5,108,420

Marks

[45] Date of Patent: Apr. 28, 1992

[54] APERTURE OCCLUSION DEVICE

[75] Inventor: Lloyd A. Marks, Bryn Mawr, Pa.

[73] Assignee: Temple University, Philadelphia, Pa.

[21] Appl. No.: 649,593

[22] Filed: Feb. 1, 1991

[51] Int. Cl.<sup>3</sup> ..... A61B 17/00

[52] U.S. Cl. .... 606/213; 606/78;

606/151; 606/157

[58] Field of Search ..... 606/78, 151, 157, 158,  
606/215, 108, 213; 128/898, 628, 686, 843, 831

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*Primary Examiner*—Stephen C. Pellegrino

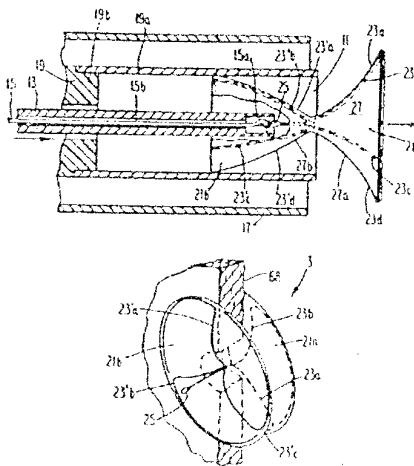
*Assistant Examiner*—Gary Jackson

Attorney, Agent, or Firm—Ratner &amp; Prestia

## [57] ABSTRACT

A device consisting of a wire for occluding an aperture within a body surface, such as atrial and ventricular septal defects (and the method of using such a device). The wire comprises two configurations, an elongated configuration for passage into said body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments, one on each side of said aperture. The wire also includes means (preferably a temperature-induced shape change) for changing the wire from the elongated configuration to the preprogrammed configuration in the body.

14 Claims, 3 Drawing Sheets

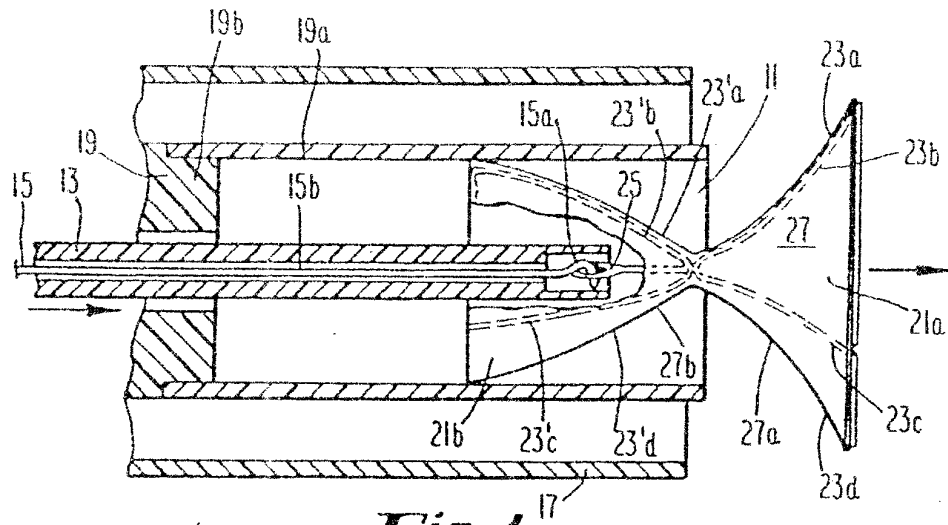


U.S. Patent

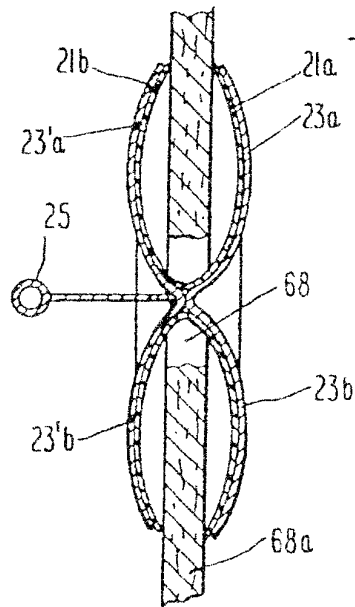
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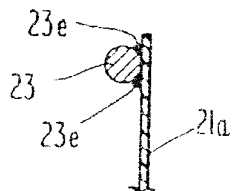
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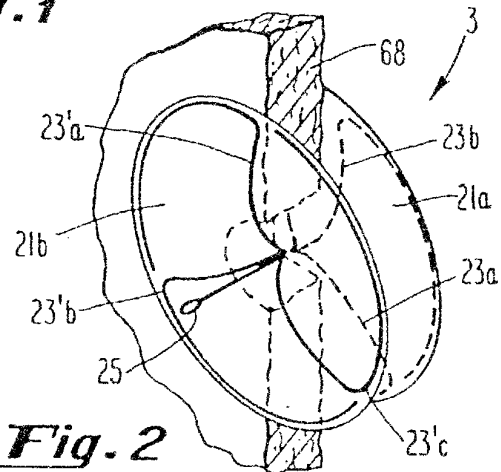
**Fig. 1**



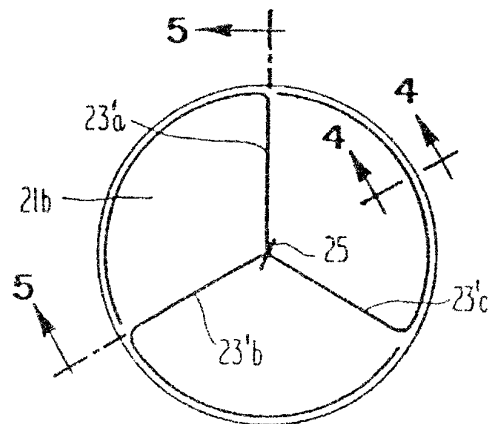
**Fig. 5**



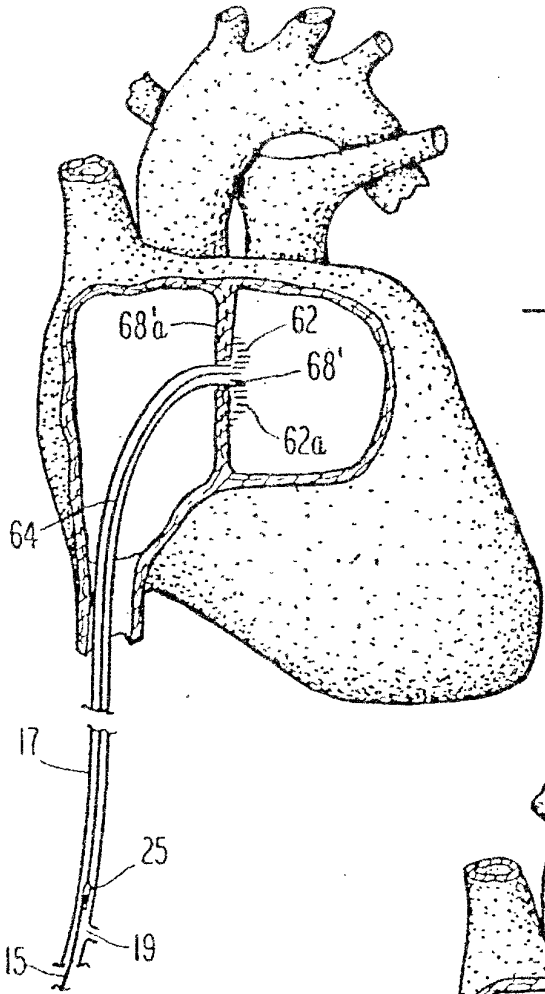
**Fig. 4**



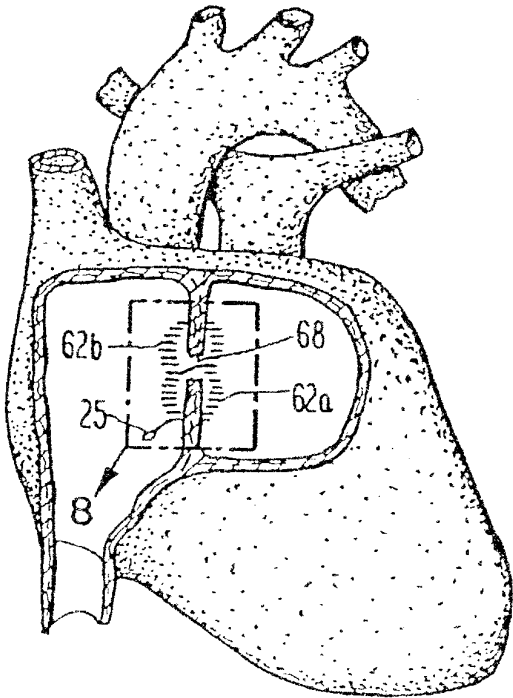
**Fig. 2**



**Fig. 3**



*Fig. 6*



*Fig. 7*

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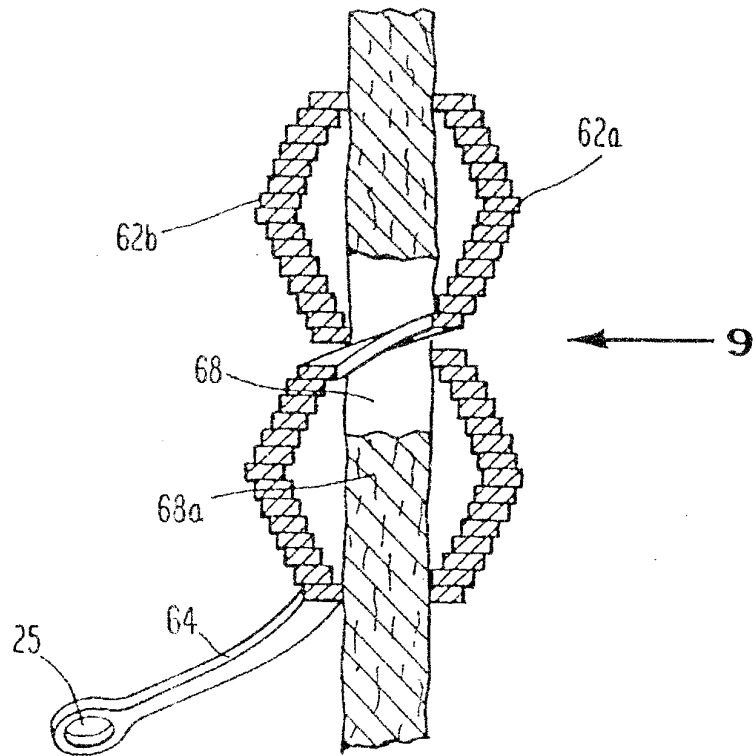


Fig. 8

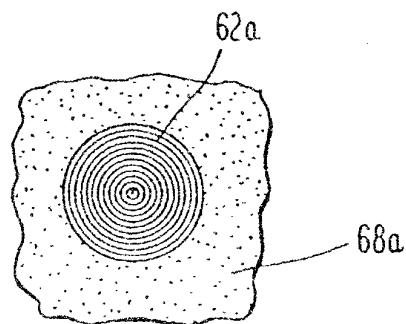


Fig. 9

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## APERTURE OCCLUSION DEVICE

### FIELD OF THE INVENTION

The invention relates to devices and methods used to occlude (i.e. block blood flow through) an aperture within a body surface; specifically, it relates to devices and methods to occlude cardiovascular septal defects.

### BACKGROUND OF THE INVENTION

It is often necessary to occlude a defect or an aperture within a body surface, such as a wall or membrane separating cavities within the body. A typical example is a congenital heart lesion called an atrial septal defect. This is a hole, between the two upper chambers of the heart, which must be closed.

King et al., U.S. Pat. No. 3,874,388, and Blake, U.S. Pat. No. 4,007,743 disclose a stainless steel apparatus for closing a shunt in the vascular system. The dual umbrella apparatus has six ribs which retain the umbrella in an open position. The King et al. apparatus has "barbs" at the ends of the ribs anchor onto the tissue surrounding the shunt. Alternatively, the barbs on the ribs of one umbrella may insert into holes on the ribs of the second umbrella, see FIG. 15A. The Blake apparatus has pivotally mounted struts which provide a flat surface to which a disk may be secured.

In "A New Percutaneous Vena Cava Filter", Cragg et al. disclose a filter composed of nitinol which when inserted into the inferior vena cava, traps emboli and clots. In the process of placing the filter, there is the threat of dislodging thrombi when the catheter or guide wire is advanced too far.

Lock et al., in *Circulation*, disclose a spring-loaded clamshell occluder of several sizes. The tension in the arms is manually controlled during delivery such that the arms of the distal umbrella, the one inserted first, are everted during placement, creating a cone.

The Rashkind occluder has two polyurethane foam disks mounted on surgical steel wire assemblies. The occluder is used to seal off the ductus arteriosus and is disclosed in *Circulation*, Vol. 75., page 583, *American Journal of Cardiology*, Vol. 64, page 218, and *Circulation*, Vol. 77, page 1068.

Devices currently used to occlude septal defects, including those indicated above, have been known to dislodge and embolize.

### BRIEF DESCRIPTION OF THE INVENTION

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, pre-programmed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the pre-programmed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being pre-programmed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("pre-programmed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or mem-

branes within the body or abnormally patent blood vessels may be similarly occluded.

In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes, one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Also included in the invention is a method for occluding an aperture by positioning a catheter at the distal side of the aperture and deploying a wire therethrough in an elongated configuration, (with the aid of a means for holding the wire) to the distal side of the aperture. Upon exiting the catheter, the wire converts to a pre-programmed configuration including an occlusion-forming wire segment on the distal side of the aperture. Upon continued deployment in the elongated configuration, the wire is permitted to assume the preprogrammed configuration including an opposing occlusion-forming wire segment on the proximal side of the aperture, with the two segments pressing toward one another. The wire is then disengaged from the means for holding the wire.

### BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic cross-sectional view, during deployment, of one embodiment of the aperture occlusion device of the claimed invention;

FIG. 2 is a perspective view of another aperture occlusion device of the present invention in a fully deployed configuration;

FIG. 3 is planar view of the device shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view, in the plane 4-4 of FIG. 3;

FIG. 5 is a cross-sectional view, in plane 5-5, of the fully deployed aperture occlusion device shown in FIG. 3;

FIG. 6 is a perspective view of a heart, partially in cross-section, schematically showing an atrial septal defect and an occlusion device of the present invention partially deployed;

FIG. 7 is similar to FIG. 6, with the occlusion device fully deployed;

FIG. 8 is an enlarged cross-sectional view of the deployed aperture occlusion device shown in FIG. 7;

FIG. 9 is a planar view of the aperture occlusion device of FIG. 8.

### DETAILED DESCRIPTION OF THE INVENTION

The invention includes devices and methods for occluding apertures in body surfaces, such as walls or membranes; the devices are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. Fallopian tubes may also be occluded by using the devices and methods of the claimed invention. Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted

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vascular communication such as a patent ductus arteriosus.

An essential part of the present invention is a wire having two configurations, an elongated configuration or folded configuration for passage into the body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments one on each side of the aperture. This wire also includes a means for causing it to change from the elongated configuration to the preprogrammed configuration inside the body. The device may also be combined with a catheter means for introducing the wire into the body. The catheter includes means for holding the wire, such as a release wire, while it is in the catheter and before it has been stimulated to convert to the preprogrammed configuration.

Preferably the wire is composed of a shape memory retentive material, such as nitinol, which causes the wire to change configurations, in response to a temperature change and which enables the wire to be activated at body temperature (having previously been at a different temperature) to assume a preprogrammed configuration. Spring steel may also serve this purpose. Furthermore, the wire must be biocompatible, and may be coated with Teflon, fibrin or endothelial cells, for example.

The occlusion forming wires may be associated with a foldable membrane, either by being embedded in the membrane or secured (by glue, stitches, staples or the like) to the surface thereof. In this embodiment, the membrane is transportable through a catheter in a folded configuration along with the wire. The occlusion-forming wires are adapted, upon converting to preprogrammed configuration, to unfold the membranes and to form a frame to support the membranes as domed or umbrella-shaped members on each side of the aperture. In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.

Referring to FIG. 1, there is shown a partially deployed stage of one aperture occlusion device. As would be used for the occlusion of a septal defect, sheath 17 (a large catheter), after entering the body in a conventional manner, such as through a femoral vein, enters the heart via the inferior vena cava and is positioned on the distal side of an atrial septal defect in the body of the left atrium.

Release wire 15, including shaft 15b and knuckle 15a, device engaging catheter 13 and aperture occlusion device 27, all disposed within deployment catheter 19, are prepared as a unit prior to deployment through sheath 17 and introduced into the body either along with or later through sheath 17.

Aperture occlusion device 27 is composed of two biocompatible membranes 21a and 21b, each comprised of a thin polyurethane membrane film, for example. Preprogrammed shape memory retentive, wire ribs 23 and 23' are secured (and may be threaded, sewn or sandwiched) to each biocompatible membrane 21a and 21b. Eye 25, attached to wire ribs 23 and 23', extends from the center of aperture occlusion device 27 and engages knuckle 15a of release wire 15. One half of aperture occlusion device 27b is seen in the folded state; upon release from deployment catheter 19 and contact with body temperature, the membrane expands between the ribs, as shown by device half 27a with associated ribs 23. In FIG. 1, four wire ribs, 23a-d and 23'a-d, on

each half of device 27, unfold, i.e. are converted from their elongated configuration to a second preprogrammed configuration, such as by a thermally stimulated shape change to a preprogrammed configuration, which urges the wire ribs outwardly, to expand and release. For this purpose, ribs 23a-d and 23'a-d are composed of a thermally responsive shape, shape memory retentive material, such as nitinol.

For transport to the site of deployment, the unit including release wire 15, device engaging catheter 13 and aperture occlusion device 27 are channeled into pod 11 of deployment catheter 19. Deployment catheter 19 includes an inner plastic portion 19b integrally connected to outer metal portion 19a. Release wire 15, device engaging catheter 13 and aperture occlusion device 27 are retained together and folded in deployment catheter 19. In practice, device 27 may be deployed without the use of deployment catheter 19, so long as sheath 17 is in a cold environment thus prohibiting device 27 from forming the preprogrammed shape.

In use, the assembly including release wire 15, device engaging catheter 13, aperture occlusion device 27 and deployment catheter 19 are passed through sheath 17 until the distal half of device 27 is disposed on the distal side of the septal defect (i.e. "aperture") to be occluded. Device engaging catheter 13, release wire 15, and aperture occlusion device 27 are maintained in place on the distal side of the defect while sheath 17 is retracted back through the defect to the proximal side thereof. Device engaging catheter 13 and release wire 15 are advanced freeing 27a to expand to preprogrammed shape. This enables a thermally stimulated shape change to the preprogrammed deployed configuration of ribs 23a-d. One-half of aperture occlusion device, 27a, is thus deployed on the distal side of the septal defect.

Coincident with the pull-back movement of deployment catheter 19 either in the preceding step or in the following step, sheath 17 is also retracted away from the aperture to be occluded.

Aperture occlusion device 27 is then pulled taut against the defect such that four wire ribs 23a-d expand and contact the heart tissue around the defect. Optionally, sheath 17 is then pulled back further away from the proximal side of the defect (if that had not been done earlier), and deployment catheter 19 is retracted leaving device engaging catheter 13, release wire 15, and aperture occlusion device 27 in place and thus exposing aperture occlusion device half 27b on the proximal side of the defect, at which point the second half 27b of device 27 is deployed.

Once aperture occlusion device 27 is fully deployed, as seen in FIGS. 2-5, knuckle 15a is disengaged from eye 25 of aperture occlusion device 27, by retracting catheter 13 slightly from eye 25. The assembly including deployment catheter 19, device engaging catheter 13 and release wire 15 are then retracted from sheath 17. Finally, sheath 17 is also retracted from the body.

FIG. 2 depicts a perspective view of an aperture occlusion device, with 3 ribs, like that seen in FIG. 1, but fully deployed to occlude a defect or aperture 68 in wall 68a. Membranes 21a and 21b are supported by wire ribs 23a-c and 23'a-c respectively, which urge the membranes toward each other and connect the membranes with eye 25.

As seen in FIG. 3, membrane 21a is attached to three wire ribs 23a, b and c extending circumferentially then curving and radially extending to the center of membrane 21a. Ribs 23a-c attach at the center of membrane

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21a and connect the pair to each other and to eye 25 which attaches to a release wire, not shown. Ribs 23a-c, upon thermal triggering of the memory retentive properties of the rib material (preferably nitinol), support and maintain the shape of membrane 21a. Membrane 21b is similarly retained by ribs 23'a-c.

FIG. 4 is a cross-section through plane 4-4 of FIG. 3. As depicted therein, membrane 21a is secured to rib 23a by glue 23c. Stitches, staples or the like may also be used to affix membrane 21a to rib 23a. Other configurations of ribs 23a, b, c may also be used.

FIG. 5 illustrates a cross-section along plane 5-5 of the aperture occlusion device of FIG. 3. Membranes 21a and 21b occlude aperture 68 in wall 68a, and are supported by wire ribs, 23a, b and 23'a, b, which urge the membranes toward each other and connect the membranes with eye 25.

FIG. 6 depicts septal defect 68' with a double helix occlusion device 62 partially deployed. Device 62 is introduced as a straight wire 64 through the assembly including, device engaging catheter 13 (like that shown in FIG. 1, but not shown in FIG. 6 due to limited space available), release wire 15 and sheath 17. Sheath 17 is diametrically larger than device engaging catheter 13 to allow passage of device engaging catheter 13 there-through. As with the assembly shown in and described with respect to FIG. 1, the assembly of release wire 15, device engaging catheter 13, wire 64 and sheath 17 are introduced through a large vein to and through the defect to be occluded. Sheath 17 optionally may be stopped short of defect 68' and may be withdrawn with device engaging catheter 13, as described, or independently of catheter 13.

Helix 62a is formed on the distal side of defect 68', preferably by the coiling of wire 64, nitinol for example, in response to a temperature change, upon body temperature contact or by retraction of spring steel into its "relaxed" (preprogrammed) configuration. A plurality of coils of progressively smaller diameter are formed, finally contacting the periphery of atrial wall 68a' surrounding defect 68' on the distal side thereof; each such coil of wire 64 contacts the previously formed coil above and below defect 68', such that helix 62a is deployed from the outside in, (relative to defect 68), until helix 62a is formed (as seen in FIG. 6).

The aperture occlusion device of FIG. 6 after deployment into the left atrium is seen in FIG. 9. The concentric circles are the result of the coiling of wire 64 (in this case from a very small starting circumference out) and also contacting the previously formed coil above and below defect 68', this time on the proximal side thereof.

After deploying helix 62a on the distal side of defect 68, sheath 17, device engaging catheter 13, release wire 15, and wire 64 are withdrawn equally and together to bring helix 62a into firm contact with the septal surface. As tension is maintained on wire 64 via release wire 15, sheath 17 is withdrawn over wire 64 and release wire 15, thereby exposing a length of wire 64 on the proximal side of the defect. Tension on wire 64 is then slowly reduced by advancing release wire 15 and sheath 17 equally and together. Wire 64 begins coiling at or near septal surface below defect 68. By progressively reducing tension on wire 64 (by repetitively withdrawing sheath 17 over release wire 15 and advancing sheath 17 and release wire 15 equally and together), successive coils are formed, each moving outward beyond the previously formed coil. Thus, helix 62b is formed from the inside out, until helix 62b is fully deployed as seen in

FIGS. 7 and 8. Eye 25 is then disengaged from the release wire 15 (not shown), and the remaining apparatus is removed from the body as described with respect to FIG. 1.

In those embodiments dependent upon a thermally responsive change (such as with nitinol) as the means for effecting device deployment, it is desirable prior to deployment to continuously infuse a biocompatible fluid (such as normal saline) which is substantially below body temperature (for example at room temperature) through side port 19 of sheath 17 to maintain a thermal environment within sheath 17, that is below the transition temperature of the thermally responsive wire 64. This assures that wire 64 will not assume its programmed shape until it exits sheath 17.

Furthermore, the programmed deployed configuration of the double helix coil (in the embodiment of FIGS. 6-9) may preferably include shaping to urge the outermost coils of helices 62a and 62b inward toward the septal surface (and one another) to provide an increased frictional force between the helices and their respective septal surfaces.

By way of general description of the method of this invention, the device of the present invention may be used in a method of occluding an aperture within a body surface. A catheter, which can accommodate a wire in an elongated or folded configuration (optionally with an associated membrane), is introduced through a body member such as a femoral vein, deployed, for example, into the heart through the inferior vena cava and manipulated into position on the distal side of the aperture where the wire assumes its preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the distal side of the septal defect. Withdrawing the catheter partially over the wire allows a substantial length of the wire to be exposed on the near side of the defect. Upon further deployment, the wire assumes a preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture. The wire is then disengaged from the means for holding it.

The device and method of this invention are believed to be particularly well adapted to occlude both atrial and ventricular septal defects, as well as other cardiovascular openings, such as a patent ductus arteriosus. The device (modified for tubal rather than aperture occlusion) is also well suited for use in occluding fallopian tubes.

In the embodiments disclosed, the finished structure comprises two connected occlusion-forming wire segments, disposed on opposite sides of an aperture, each formed of a wire resulting in helices, or domed members (with membranes attached to a wire frame), urged toward one another.

While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and equivalent variations of this invention may be devised by those skilled in the art without departing from the true spirit and scope of this invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

What is claimed is:

1. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter

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ter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture urged toward one another and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, said means being a temperature responsive material of construction of said wire, by which said wire is activated at body temperature, to assume said preprogrammed configuration.

2. A device of claim 1 wherein said wire is combined with a catheter means for introducing said wire into said body, said catheter means also includes means for holding said wire, while it is in said catheter, at a temperature at which said wire does not tend to assume said preprogrammed configuration.

3. A device of claim 1 wherein said occlusion-forming segments each comprise helical coils urged toward one another.

4. A device of claim 1 wherein said wire further includes two foldable membranes, one associated with said first occlusion-forming wire segment and the other associated with said second occlusion-forming wire segment, said membranes in folded configuration being transportable through a catheter along with said wire, said wire adapted upon converting from said elongated configuration to said preprogrammed configuration to unfold said membranes and to form a frame supporting said membranes as essentially planar members, one disposed on each side of said aperture, and urged toward one another, wherein said means for causing a change in configuration is a thermally responsive material of construction.

5. A device according to claim 4 wherein said wire is secured to said membranes of said occlusion-forming wire segments.

6. A device according to claim 1, wherein said wire consists of nitinol.

7. A device according to claim 1, wherein said wire is biocompatible.

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8. A device according to claim 1, wherein said wire is coated to enhance biocompatibility.

9. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture, and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, wherein said occlusion forming segments each comprise helical coils urged toward one another.

10. A device according to claim 9, wherein said wire consists of spring steel.

11. A method for occluding an aperture within a body surface by positioning the end of a catheter at the distal side of the aperture, deploying a wire of temperature responsive material of construction in an elongated configuration through said catheter to the distal side of said aperture with the aid of a means for holding said wire, permitting the wire exposed thereby to assume a preprogrammed configuration, including an occlusion-forming wire segment on the distal side of said aperture, and urged toward said aperture, withdrawing the end of said catheter through said aperture and deploying an additional length of said wire in an elongated configuration to be exposed on the proximal side of said aperture, whereupon said continued deployment, said wire is permitted to assume a preprogrammed configuration, including an opposing occlusion-forming wire segment urged toward said aperture on the proximal side of the aperture, and disengaging the wire from the means for holding said wire.

12. A method as recited in claim 11, wherein said defect is a atrial septal defect.

13. A method as recited in claim 11, wherein said defect is a ventricular septal defect.

14. A method as recited in claim 11, wherein said defect is a patent ductus arteriosus.

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**EXHIBIT J**

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## CONFIDENTIAL TREATMENT REQUESTED

Exhibit 10.17

### AGREEMENT

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THIS AGREEMENT made and entered into as of this 15th day of April, 1996, by and between Nitinol Medical Technologies, Inc., a Delaware Corporation having a place of business at 263 Summer Street, 7th Floor, Boston, Massachusetts 02210 (hereinafter called NITINOL) and Lloyd A. Marks, residing at 301 Roanoke Road, Westfield, New Jersey 07090 (hereinafter called MARKS).

### WITNESSETH:

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WHEREAS, MARKS has made and is making certain inventions, modifications and improvements relating to an aperture occlusion device for occluding an aperture within a body surface, including the inventions defined by United States Patent No. 5,108,420 owned by MARKS (hereinafter COVERED INVENTIONS);

WHEREAS, NITINOL desires to develop and commercially exploit such COVERED INVENTIONS in the United States and abroad.

WHEREAS, NITINOL desires to acquire an exclusive right under the COVERED INVENTIONS, including the existing U.S. patent owned by MARKS and future patents for improvements to the method or apparatus defined by such existing U.S. patent to manufacture, use and sell devices embodying the COVERED INVENTIONS and the exclusive right to grant sublicenses to others to do so;

NOW THEREFORE, in consideration of the mutual promises and conditions set forth herein, the parties agree as follows:

### ARTICLE I - DEFINITIONS

-----

1. LICENSED PRODUCTS shall mean devices and method manufactured, used or sold by NITINOL and sublicenses of NITINOL which are covered by U.S. Patent No. 5,108,420 and/or the claims of any patent owned by MARKS for the COVERED INVENTIONS which is licensed by NITINOL hereunder.

2. LICENSED PATENTS shall mean any patent owned by MARKS covering LICENSED PRODUCTS and licensed hereunder by NITINOL.

3. TECHNICAL INFORMATION means advise and data, both oral and written, as to processes, formulae, designs and operation, including operating techniques, product specifications, plans, drawings and sketches, know how, trade secrets and proprietary data both patentable and unpatentable, computer programs, algorithms and other materials or information relating to aperture occlusion devices for occluding an aperture within a body surface and devices and methods for use thereof which is presently possessed by, or hereinafter developed or acquired by MARKS during the term of this Agreement, which MARKS is free to disclose to NITINOL, and which information  
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#### CONFIDENTIAL TREATMENT REQUESTED

is applicable and necessary to assist NITINOL in the commercial production, use and sale of LICENSED PRODUCTS.

4. NET SALES PRICE shall mean the total gross sales price charged and collected by NITINOL and sublicensees of NITINOL for LICENSED PRODUCTS less any transportation charges included in said gross sales price, any normal trade discounts allowed to customers at the time of sale, any sales, use or excise taxes imposed and actually paid which were included in said gross sales price, any credits or allowances given or made on account of rejection or return of LICENSED PRODUCTS previously delivered.

#### ARTICLE II - GRANTS

-----

1. MARKS warrants that he is the owner of all right, title and interest in U.S. Patent No. 5,108,420 and hereby grants to NITINOL, subject to the provisions of this Agreement and on the royalty basis hereinafter stated, an exclusive worldwide license to make use and sell LICENSED PRODUCTS and the exclusive right to sublicense others to make use, and sell LICENSED PRODUCTS.

2. MARKS hereby grants to NITINOL the right of first refusal for an exclusive license under future patents owned by MARKS (LICENSED PATENTS) for COVERED INVENTIONS in accordance with the terms of this Agreement, to

manufacture, use and sell devices and methods covered by such patents and the exclusive right to sublicense others to do so.

### ARTICLE III - PAYMENTS

-----

1. NITINOL agrees to pay to MARKS for the licenses and other rights granted herein:
  - a. A payment of XXXXXXXXXXXX upon execution by both parties of this Agreement.
  - b. A payment, to be made promptly after the execution of this Agreement to Temple University of Philadelphia, Pennsylvania, in an amount sufficient to reimburse Temple University for costs which it incurred in obtaining U.S. Patent No. 5,108,420, or in the amount of eighteen thousand eighty eight (\$18,088) dollars, whichever is less.
  - c. Royalties for each calendar year of this Agreement based on the NET SALES PRICE of LICENSED PRODUCTS sold by NITINOL and its sublicensees in the United States during such calendar year in an amount equal to XXXXXXXXXXXX of the NET SALES

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PRICE of all LICENSED PRODUCTS sold during each calendar year in the United States;

- d. NITINOL agrees to pay to MARKS as long as this Agreement is in effect a minimum annual royalty based upon the following schedule:
  - (i) For the first one year period between the date of this Agreement and the one year anniversary date, a minimum royalty payment of XXXXXXXXXXXX is due and owed on the one year anniversary date;
  - (ii) For the second one year period beginning on the one year anniversary date and ending on the second year anniversary date of this Agreement, a minimum royalty of XXXXXXXXXXXX is due and owed on the second year anniversary date;

- (iii) For the third one year period beginning on the second year anniversary date and ending on the third year anniversary date, a minimum royalty of XXXXXXXXXXXX is due and owed on the third year anniversary date;
- (iv) For the fourth one year period beginning on the third year anniversary date and ending on the fourth year anniversary date, a minimum royalty of XXXXXXXXXXXX is due and owed on the fourth year anniversary date;
- (v) For the fifth one year period beginning on the fourth year anniversary date and ending on the fifth year anniversary date, a minimum royalty of XXXXXXXXXXXX is due and owed on the fifth year anniversary date.
- (vi) For the sixth one year period beginning on the fifth year anniversary date and ending on the sixth year anniversary date, a minimum royalty of XXXXXXXXXXXX is due and owed on the sixth year anniversary date;
- (vii) For each one year period subsequent to and beginning with the sixth year anniversary date, a minimum annual royalty of XXXXXXXXXXXX is due and owed on each subsequent one year anniversary date.

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#### CONFIDENTIAL TREATMENT REQUESTED

- e. NITINOL agrees to accomplish the following development activities funded by NITINOL relative to at least one LICENSED PRODUCT in accordance with the following timetable;
  - (i) During the first one year period between the date of this Agreement and the first year anniversary date -- completion of a prototype;
  - (ii) By the end of the two year period between the date of this Agreement and the second year anniversary date, initiate animal experiments, at least some such experiments will be performed by MARKS at a center selected by NITINOL in collaboration with MARKS.
  - (iii) By the end of three year period between the date of this

Agreement and the third year anniversary date -- complete the animal experiments;

(iv) By the end of the four year period between the date of this Agreement and the fourth year anniversary date -- initiate human clinical trials. MARKS will participate in at least some of such clinical trials.

- f. If NITINOL fails to achieve by an anniversary date set forth in Article III, paragraph 1e, the development activity scheduled to be achieved by that anniversary date, NITINOL may retain the exclusive license granted hereunder by XXXXXXXXXXXX the minimum royalty payment due and owed on such anniversary date under Article III, paragraph 1d. If NITINOL fails to make this XXXXXXXXXXXX payment of the minimum royalty for the year in question, the exclusive license granted hereby is terminated.
- g. The minimum annual royalty set forth in Article III(d) and (f) shall be deductible from royalties payable under Article III(c) by NITINOL in the twelve (12) months after the anniversary date on which the minimum royalty is paid.
- h. Upon execution by both parties of this agreement, NITINOL grants to MARKS warrants to purchase up to ten thousand (10,000) shares of NITINOL common stock at a price of one cent (.01) per share.

2. Should NITINOL, due to its manufacture, use or sale of LICENSED PRODUCTS, be sued for infringement of a U.S. patent owned by a third party, NITINOL will escrow the minimum royalties due MARKS

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under Article III, paragraph 1d, hereof pending a final decision in the infringement litigation, and, for the duration of the litigation, shall be relieved from meeting the development activity due dates of Article III, paragraph 1e, and the penalties of paragraph 1f.

#### ARTICLE IV - RECORDS, REPORTS AND PAYMENTS

-----

1. NITINOL agrees to keep full, true and accurate records and books of account in sufficient detail to permit convenient calculations of the royalties payable hereunder by NITINOL and its sublicensees. NITINOL agrees to permit its books and records to be examined during normal business hours upon reasonable

notice by MARKS by an auditor, accountant or other agent appointed or employed by MARKS to verify the accuracy of the reports provided for in Paragraph 2 of this Article.

2. NITINOL agrees to report to MARKS for each calendar quarter between the anniversary dates of this Agreement not later than thirty (30) days following the last day of each such calendar quarter during the term hereof the total number of LICENSED PRODUCTS that were sold by NITINOL and its sublicensees during the preceding calendar quarter. Each such report shall be accompanied by full payment of the total royalty due hereunder to MARKS from NITINOL for said preceding quarter.

3. In the event of termination of this Agreement, NITINOL, within sixty (60) days after the date of such termination, shall furnish to MARKS a written statement setting forth its total Net Sales of LICENSED PRODUCTS during the preceding calendar quarter to the date of termination and will concurrently with the submission of such report pay the royalties due to the date of termination.

#### ARTICLE V - TECHNOLOGY TRANSFER

-----

1. After the execution of this Agreement, MARKS agrees to make available to NITINOL, so far as possible, TECHNICAL INFORMATION including product information, specifications and drawings in MARKS' possession which NITINOL deems necessary or useful for the manufacture, use, sale and installation of LICENSED PRODUCTS. MARKS shall respond as promptly as reasonably possible to all requests by NITINOL for TECHNICAL INFORMATION.

2. MARKS shall use reasonable care in communicating TECHNICAL INFORMATION including advise, drawings, opinions and the like as herein provided to NITINOL, but in no event shall MARKS incur any liability whatsoever for the accuracy thereof or in any way relating thereto so long as MARKS shall have made good faith efforts to provide accurate and complete TECHNICAL INFORMATION.

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3. MARKS shall maintain all patents on inventions covering LICENSED PRODUCTS.

#### ARTICLE VI - PATENT ENFORCEMENT

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1. NITINOL retains the right to take legal action and recover against any and all infringers of LICENSED PATENTS. MARKS shall not be entitled to any

damages, recovery or royalties resulting from any such legal action conducted solely by NITINOL, but MARKS agrees to cooperate with NITINOL in such action but at no expense to MARKS. However, MARKS shall have the right to take legal action at his own expense regarding infringements of patents licensed by MARKS to NITINOL hereunder if NITINOL takes no action to terminate such infringement within six months after notice thereof is given to NITINOL by MARKS, or if NITINOL provides notice to MARKS that no such action will be taken by NITINOL. NITINOL shall not be entitled to any damages, royalties or recovery resulting from any such legal action conducted solely by MARKS. NITINOL agrees to cooperate with MARKS in such action, but at no expense to NITINOL.

#### ARTICLE VII - CANCELLATION, TERMINATION

-----

1. If NITINOL shall fail to refuse to make any payments due to MARKS hereunder, or refuse to comply with any other material provision hereof, and if any such default in the making of such payment or in complying with such other provisions shall continue unremedied for sixty (60) days after a written default notice is given to NITINOL by MARKS of such default and the default is not contested in writing by NITINOL, then MARKS, after the expiration of said sixty (60) days and for so long as such default shall continue unremedied, may elect at his option to terminate this Agreement by providing a written termination notice to NITINOL.

2. If NITINOL, in good faith, contests any payments claimed by MARKS to be due or other alleged defaults by NITINOL outlined in a default notice given under Article VII, paragraph 1, NITINOL shall set forth the basis for contesting such payments or alleged defaults in writing within sixty (60) days from the receipt of the default notice from MARKS. In the event this occurs, MARKS will not terminate this Agreement and a good faith effort will be made by both parties to settle the dispute involving the contested payment or default, and should this effort fail, the arbitration procedure of Article XIV hereof will be instituted.

3. If MARKS shall fail or refuse to comply with any material provision hereof and if such default in compliance shall continue unremedied for sixty (60) days after a written default notice is given to MARKS by NITINOL of such default, and the default is not contested in writing by MARKS, then NITINOL, after the expiration of said sixty (60) days and for so long as such default shall continue unremedied, may elect at its option to terminate the minimum royalty provisions of this Agreement and to reduce the percentage royalty of Article III, paragraph 1c

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to XXXXXXXXXXXX by providing written notice thereof to MARKS or alternatively to terminate this Agreement by providing a written termination notice to MARKS.

4. If MARKS, in good faith, contests the alleged defaults outlined in the default notice given under Article VII, paragraph 3, MARKS shall set forth the basis for contesting such alleged defaults in writing within sixty (60) days from the receipt of the default notice from NITINOL. In the event this occurs, NITINOL will not terminate this Agreement or reduce the royalty percentage and a good faith effort will be made by both parties to settle the dispute involving the contested defaults. Should this effort fail, the arbitration procedure of Article hereof will be instituted, and during such arbitration procedure, NITINOL will escrow any royalties due hereunder pending a final decision.

5. If U.S. Patent No. 5,108,420 and all LICENSED PATENTS by MARKS are declared invalid in a nonappealable judicial decision, NITINOL may terminate this Agreement.

6. Unless otherwise terminated as provided in this Article or elsewhere in this Agreement, this Agreement shall continue in force until the expiration of the first to expire of the U.S. patents licensed hereunder. If additional LICENSED PATENTS are still in effect covering LICENSED PRODUCTS, the parties hereby agree to negotiate a new license for these patents at a royalty not in excess of that set forth in Article III hereof.

7. Termination of this Agreement shall not affect any rights accrued or obligations incurred prior to the effective date of such termination.

### ARTICLE VIII - PROTECTION OF DATA AND INFORMATION

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1. The TECHNICAL INFORMATION or other information identified as confidential which is furnished or disclosed by either party hereunder to the other, is for the sole use of the party receiving such disclosure. The party receiving confidential information will insure that information in written, printed, oral or other form, received from the other party hereunder, shall not be disclosed to third parties without the consent of the disclosing party except insofar as such information:

- a. Is necessarily disclosed solely by its use in LICENSED PRODUCTS or products manufactured and sold by the receiving party and its sublicensees;

- b. Is made public by the party providing the confidential information;

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- c. Is established to be in the public domain otherwise than as a consequence of a breach of the obligation here under taken not to disclose the information;
- d. Is in the possession of the receiving party prior to its receipt and the receiving party possesses documentary evidence to establish this fact;
- e. Must reasonably be disclosed by the receiving party to its sublicensees to enable them to manufacture, use or sell LICENSED PRODUCTS; and in all such cases, the receiving party shall require its sublicensees to maintain such information to confidence to the extent of the foregoing requirements of this Article;
- f. Must reasonably be disclosed by the receiving party to its suppliers as essential to their tender or performance of work for such party under this Agreement, and in all such cases the receiving party shall require its suppliers to use such information solely for the performance of work for the receiving party and to maintain such information in confidence to the extent of the foregoing requirements of this Article.

2. Upon the termination of this Agreement for any reason, all written confidential information within the possession of either party which was received from the other party will be returned within ninety (90) days of the termination date.

#### ARTICLE IX - PRODUCT LIABILITY

-----

1. NITINOL assumes total product liability for the manufacture, use and sale of said LICENSED PRODUCTS by NITINOL. NITINOL agrees to indemnify and save harmless MARKS from every claim, demand, expense and cost, including attorneys' fees, which may arise by reason of the LICENSED PRODUCTS manufactured or sold by NITINOL and any injury or damage of any kind or nature to any person or property claimed to have been caused by or resulting from or arising out of a defect in design, workmanship or material of any LICENSED PRODUCT manufactured or supplied by NITINOL in accordance with this Agreement.

2. NITINOL, at its expense, shall obtain and maintain in effect during the term of this Agreement appropriate liability insurance covering LICENSED PRODUCTS in such amount and against such risks as are obtained and maintained by companies similarly situated, such insurance to specifically identify and cover MARKS, and to be in an amount no less than \$4,000,000.

#### ARTICLE X - REGULATORY CLEARANCES

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1. NITINOL shall assume, within the limits of reasonable corporate prudence and at its expense, the primary responsibility for obtaining F.D.A. and other regulatory clearances as may be required for LICENSED PRODUCTS.

2. NITINOL, at its own expense, will seek term extensions of patents covering LICENSED PRODUCTS if such are available under laws allowing such extensions for medical products subjected to prolonged regulatory approval time which shorten the effective life of the patent.

#### ARTICLE XI - ASSIGNMENT

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1. This Agreement may be assigned by MARKS after notice of such assignment is given to NITINOL and approved by NITINOL, such approval not to be unreasonably withheld, and subject to the condition that such assignee shall have, by a writing delivered to NITINOL, expressly assumed all of the obligations and liabilities of MARKS under this Agreement and agreed to be bound by all of the terms and provisions hereof.

2. This Agreement may be assigned by NITINOL after notice of such assignment is given to MARKS and approval by MARKS, such approval not to be unreasonably withheld, subject to the condition that such assignee shall have, by a writing delivered to MARKS, expressly assumed all of the obligations and liabilities of NITINOL under this agreement and agreed to be bound by all of the terms and conditions hereof.

3. Any assignment not made and approved in accordance with Article XI, paragraphs 1 and 2, is null and void.

#### ARTICLE XII - WARRANTY

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MARKS represents and warrants that U.S. Patent No. 5,108,420 has been assigned to him; that he has good and valid title to this patent, free and clear of any claims, liens, pledges, etc.; that he knows of no adverse claim made or threatened either to the effect that the patent is invalid or that the device disclosed therein infringes upon any other United States or foreign patent; and that MARKS has full power and authority to enter into this Agreement.

#### ARTICLE XIV - ARBITRATION

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1. The parties shall arbitrate disputes in accordance with the Arbitration Rules of the American Arbitration Association (AAA) insofar as they are not modified by the following provisions.

2. Scope of Arbitration. All controversies or claims arising out of or relating to this agreement, or the breach thereof, shall be subject to arbitration pursuant to this section.

3. Initiating Arbitration. To initiate arbitration, the aggrieved party shall first provide written notice to the other party specifying the issues in dispute and its position on those issues. Such notice must be given while the Agreement is in effect or within three years after the termination of this Agreement, or the aggrieved party's right to redress is entirely waived. Within 14 days of receipt of the notice, the receiving party shall make written response specifying its position on the issues in dispute, and the parties shall in good faith attempt to negotiate a solution to the controversy for a further period of 14 days after the written response. If no written response is filed or the dispute is not resolved during the negotiation period, the aggrieved party shall file a demand for arbitration in writing with the other party and with the AAA.

4. Effect of Arbitration. The initiation of arbitration by written notice as specified above shall toll any statute of limitations applicable to the dispute. The parties will continue to comply with all provisions and requirements of this Agreement pending the outcome of arbitration.

5. Form of Arbitration. One neutral arbitrator shall be appointed by the AAA, and except as otherwise provided herein, all decisions and awards shall be made by the Arbitrator.

6. Arbitration Management. It shall be the Arbitrator's responsibility to exert management initiative and control over the arbitration, including discovery and scheduling, so that a just decision is reached as quickly as possible and at minimum expense to the parties. The Arbitrator will manage and schedule proceedings, make orders and issue subpoenas for discovery, establish protective orders to maintain confidentiality of proprietary information, decide discovery and evidentiary disputes, and shall enforce his orders by assessing costs and/or fines and/or directing findings on issues where appropriate. The decisions of the Arbitrator shall be final and binding.

7. Discovery. After the arbitration notice has been filed, the parties shall, before the hearing thereof, cooperate in discovery and mandatory disclosure of all matters relevant to such dispute, to the extent and in the manner provided by the Federal Rules of Civil Procedure, including making their employees, agents, and experts available for depositions. Discovery and disclosure shall be completed within two months after filing of the notice of arbitration. The Arbitrator may extend this deadline, but only upon a showing of exceptionally good cause, and in no event shall extensions in excess of an additional two months be granted.

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8. Hearings, Award, and Judgment. All hearings shall be held at a location designated by the Arbitrator and hearings shall be completed within two months of the completion of discovery. Evidence not admissible under traditional rules of evidence may be admitted at the sole discretion of the Arbitrator, but the weight given to evidence will be limited based on its apparent reliability under traditional evidence law concepts. The Arbitrator shall render a written award within one week after the last day of hearings. The written award shall specify the final judgment of the Arbitrator without any reasons in support of the award. The award shall be final and binding on the parties as to each other, but shall have no effect as to any other party. The Arbitrator shall have the power to award any remedy provided under the applicable laws. Judgment upon the award maybe entered and enforced in any court having jurisdiction thereof at the request of either party. The parties shall treat the written award as confidential and shall not reveal its specific contents publicly or privately except to the extent required by a court order or by securities laws.

9. Cost of Arbitration. The party demanding arbitration shall pay the arbitration management fees of the AAA. Initially, the parties shall each pay 50% of the fees of the Arbitrator, and shall each bear their own costs of arbitration. However, at the time of the award, the Arbitrator shall direct the losing party to pay the other party its reasonable legal fees and other costs of arbitration unless the circumstances call for a different result.

ARTICLE XV - MISCELLANEOUS

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1. Neither party shall be obligated to disclose any proprietary information of a third party without the consent of such third party, nor any information the furnishing of which would require the payment of consideration to a third party other than an employee of the party furnishing such information.

2. If any clause or part of this Agreement should be found to be invalid for any reason, this shall not affect the effectiveness of the other clauses or parts thereof.

3. Performance of the terms and conditions of this Agreement by either party is excused whenever such performance is prevented by strike, riot, fire, war, insurrection, the elements, acts of God or the public enemy, compliance with any laws, regulation or other governmental order or other causes beyond the control of the parties.

4. This Agreement and all the provisions hereof shall inure to the benefit of, and be binding upon, the heirs, distributees, successors, assigns and legal representatives of the parties.

5. Each party shall notify the other party of any other patents or patent applications of which the notifying party becomes aware, covering any adaptations or improvements of the LICENSED PRODUCTS.

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6. Any notice required hereunder shall be in writing and shall be deemed to be properly given when sent registered mail.

7. The law of the State of New Jersey shall govern this Agreement as to all matters, including, specifically but not exclusively, matters of interpretation, performance and remedies, insofar as such law is existent or applicable and can or will be applied in the jurisdiction in which either party may seek in adjudication of any such matter.

8. This Agreement constitutes the entire understanding between the parties and conclusively supersedes all prior writings and negotiations between them. This Agreement shall not be modified unless modification is in writing and signed by both parties.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement.

LLOYD A. MARKS

/s/ Lloyd A. Marks

-----

NITINOL MEDICAL TECHNOLOGIES, INC.

By: /s/ Thomas M. Tully

-----

Title: President

**EXHIBIT K**

DEC 10 '98 14:50 FR HALE AND DORR LLP

526 5000 TO 71111#106506\*132 P.05

**Copy**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

Dec 10 12 12 PM '98

NITINOL MEDICAL TECHNOLOGIES, Inc.  
and LLOYD A. MARKS,

Plaintiffs,

v.

AGA MEDICAL CORPORATION,

Defendant.

U.S. DISTRICT COURT  
THE DISTRICT OF  
MASSACHUSETTS

Civil Action No. \_\_\_\_\_

JURY TRIAL DEMANDED

**98CV12506 NG**

COMPLAINT FOR PATENT INFRINGEMENT

**NATURE OF ACTION**

This is an action under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,108,420.

**THE PARTIES**

1. Plaintiff Nitinol Medical Technologies, Inc. ("Nitinol") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Boston, Massachusetts.
2. Plaintiff Lloyd A. Marks ("Marks") is a resident of Westfield, New Jersey.
3. Defendant AGA Medical Corporation ("AGA Medical"), is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

DEC 10 '98 14:51 FR HALE AND DURR LLP

526 5000 TO 71111#106586\*132 P.06

#### JURISDICTION AND VENUE

4. This is an action for patent infringement arising under Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a).

5. Venue is proper in this jurisdiction pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

#### ACTS GIVING RISE TO THE COMPLAINT

6. Plaintiff Marks is the inventor and owner by reassignment of United States Patent No. 5,108,420 (the "'420 patent'"), entitled "Aperture Occlusion Device." A copy of the '420 patent is attached as Exhibit A.

7. Plaintiff Nitinol is the exclusive worldwide licensee of the right to make, use and sell products embodying the '420 patent and/or manufactured according to the methods of the '420 patent.

8. Defendant AGA Medical manufactures, offers for sale or sells medical devices which infringe one or more claim of the '420 patent.

9. Defendant AGA Medical is currently making, using or selling, and will, unless enjoined, continue to make, use or sell, medical devices infringing one or more claim of the '420 patent.

10. On information and belief, Defendant AGA Medical's acts of infringement are willful and deliberate.

DEC 10 '98 14:51 FR HALE AND DORR LLP

526 5000 TO 71111#106506\*132 P.07

WHEREFORE, plaintiffs Nitinol and Marks request that judgment be entered in their favor, and that they be granted the following relief:

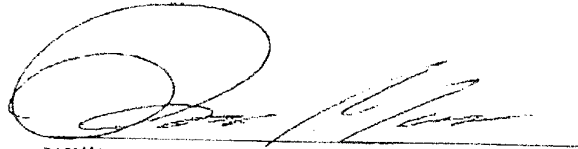
- i. A judgment that AGA Medical has infringed the '420 patent, and that such infringement has been willful;
- ii. A permanent injunction restraining AGA Medical, its officers, agents, servants, employees and those acting in concert with it, from infringing the '420 patent;
- iii. An award of damages sufficient to compensate Nitinol and Marks for the infringement complained of herein;
- iv. An award of enhanced damages in the amount of three times the damages found or assessed, attorneys' fees, disbursements and costs of suit; and
- v. Such other and further relief as the Court deems just and proper.

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY.

Dated: December 10, 1998

NITINOL MEDICAL TECHNOLOGIES,  
INC. and LLOYD A. MARKS

By their attorneys,



William F. Lee (BBO #291960)  
William G. McElwain (BBO #332510)  
Dominic E. Massa (BBO #564694)  
Hale and Dorr LLP  
60 State Street  
Boston, Massachusetts 02109  
(617) 526-6000

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CLOSED

**United States District Court  
District of Massachusetts (Boston)  
CIVIL DOCKET FOR CASE #: 1:98-cv-12506-NG**

Nitinol Medical Tech v. Aga Medical Corp.  
Assigned to: Nancy Gertner  
Demand: \$0  
Related Case: 1:04-cv-12565-NG  
Cause: 35:271 Patent Infringement

Date Filed: 12/10/1998  
Jury Demand: Defendant  
Nature of Suit: 830 Patent  
Jurisdiction: Federal Question

**Plaintiff**

**Nitinol Medical Technologies Inc.**

represented by **William F. Lee**  
Wilmer Cutler Pickering Hale and Dorr  
LLP  
60 State Street  
Boston, MA 02109  
617-526-6556  
Fax: 617-526-5000  
Email: [william.lee@wilmerhale.com](mailto:william.lee@wilmerhale.com)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Aga Medical Corporation**

represented by **James T. Nikolai**  
Nikolai & Mersereau, P.A.  
900 Second Avenue, South  
Suite 820  
Minneapolis, MN 55402-2813  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Paul T. Dietz**  
Nikolai, Mersereau & Dietz  
900 Second Avenue South  
820 International Centre  
Minneapolis, MN 55402  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Thomas C. O'Konski**  
Cesari & McKenna, LLP  
88 Black Falcon Avenue  
Boston, MA 02210  
617-951-2500

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Fax: 617-951-3927  
 Email: TOK@c-m.com  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

**Counter Claimant****Aga Medical Corporation**

represented by **Thomas C. O'Konski**  
 (See above for address)  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

V.

**Counter Defendant****Nitinol Medical Technologies Inc.**

represented by **William F. Lee**  
 (See above for address)  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

Date Filed	#	Docket Text
12/10/1998	1	Complaint filed. Case assigned to Judge: Gertner. Receipt #: 10982 Amount: \$ 150.00. Fee Status: pd (fmr) (Entered: 12/10/1998)
12/10/1998		Summons issued for Aga Medical Corp. (fmr) (Entered: 12/10/1998)
03/23/1999	2	Return of service executed as to Aga Medical Corp. with service on 3/22/99 filed. Answer due on 4/11/99 for Aga Medical Corp. (fmr) (Entered: 03/25/1999)
04/12/1999	3	Answer to complaint; jury demand and Counterclaim by Aga Medical Corp. against Nitinol Medical Tech , filed. (fmr) (Entered: 04/13/1999)
05/03/1999	4	Answer by Nitinol Medical Tech to [3-2] counter claim , filed. (fmr) (Entered: 05/04/1999)
05/11/1999	5	Motion by Aga Medical Corp. for Paul Dietz to appear pro hac vice fee status: pd fee amt: 50.00 Receipt #: 14215 , filed. (fmr) (Entered: 05/12/1999)
05/12/1999		Judge Nancy Gertner . Endorsed Order entered granting [5-1] motion for Paul Dietz to appear pro hac vice fee status: pd fee amt: 50.00 Receipt #: 14215 . (fmr) (Entered: 05/12/1999)
07/26/1999	6	Judge Nancy Gertner . Notice of Hearing/conference: set scheduling conference for 9:30 8/6/99 . (fmr) (Entered: 07/26/1999)
08/02/1999	7	Joint statement by Nitinol Medical Tech, Aga Medical Corp. , re: proposed discovery schedule, filed. (fmr) (Entered: 08/03/1999)
08/03/1999	8	Letter by Paul T. Dietz dated: 8/2/99 to: Mr McElwain re: problem with joint statement filed. (fmr) (Entered: 08/03/1999)

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08/06/1999	9	Letter by Paul T. Dietz dated: 8/2/99 to: Mr McElwain re: teleconference filed. (fmr) (Entered: 08/06/1999)
08/06/1999		Scheduling conference held . (fmr) (Entered: 08/10/1999)
08/06/1999	10	Judge Nancy Gertner . Clerk's Notes: re: scheduling conference. Counsel are to submit a new joint statement by 8/13/99. Judge will adopted as stated in conference set status conference for 2:30 7/11/00 Court Reporter: none (fmr) (Entered: 08/10/1999)
08/23/1999	11	Judge Nancy Gertner . Scheduling Order entered setting dispositive motion filing date of 12/31/00 . [EOD Date 8/24/99] (fmr) (Entered: 08/24/1999)
12/29/1999		Proposed protective order received and sent to chambers for signature (fmr) (Entered: 12/30/1999)
01/10/2000	12	Judge Nancy Gertner . Protective Order entered . [EOD Date 1/12/00] (fmr) (Entered: 01/12/2000)
01/31/2000	13	Joint motion by Nitinol Medical Tech, Aga Medical Corp. to modify discovery schedule , filed. . (fmr) (Entered: 02/03/2000)
02/20/2000		Judge Nancy Gertner . Endorsed Order entered granting [13-1] joint motion to modify discovery schedule, ready trial for 2/1/01 , set motion filing deadline for 10/31/00 . [EOD Date 2/22/00] dispositive motions, including Markman hearing due 12/29/00;cc/cl (sad) (Entered: 02/22/2000)
02/25/2000	14	Motion by Nitinol Medical Tech to compel , filed. (fmr) (Entered: 02/28/2000)
02/25/2000	15	Memorandum by Nitinol Medical Tech in support of [14-1] motion to compel , filed. (fmr) (Entered: 02/28/2000)
02/29/2000	16	Response by Aga Medical Corp. in opposition to [14-1] motion to compel , filed. (fmr) (Entered: 03/01/2000)
02/29/2000	16	Motion by Aga Medical Corp. to extend time to no date given to file opposition , filed. (fmr) (Entered: 03/01/2000)
03/06/2000	17	Motion by Nitinol Medical Tech for leave to file reply memorandum , filed. (fmr) (Entered: 03/07/2000)
03/06/2000	18	Reply/response by Nitinol Medical Tech to [16-1] opposition response , filed. (fmr) (Entered: 03/07/2000)
03/07/2000		Judge Nancy Gertner . Endorsed Order entered granting [17-1] motion for leave to file reply memorandum . [EOD Date 3/7/00] (fmr) (Entered: 03/07/2000)
03/10/2000		Judge Nancy Gertner . Endorsed Order entered granting [16-1] motion to extend time to no date given to file opposition. Motion is denied as to 7.1 (a)(2) grounds; the motion to extend time hereby granted. Opposition to be filed by 3/23/00 [EOD Date 3/13/00] (fmr) (Entered: 03/13/2000)

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03/23/2000	19	Response by Aga Medical Corp. in opposition to [14-1] motion to compel , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	20	Motion by Aga Medical Corp. to compel in accordance with the stipulated protective order , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	21	Memorandum by Aga Medical Corp. in support of [20-1] motion to compel in accordance with the stipulated protective order , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	22	SEALED Appendix/exhibits by Aga Medical Corp. in support of [21-1] support memorandum , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	23	Motion by Aga Medical Corp. for protective order , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	24	Memorandum by Aga Medical Corp. in support of [23-1] motion for protective order , filed. (fmr) (Entered: 03/24/2000)
04/05/2000		Motion to compel sent to chambers #14 (fmr) (Entered: 04/05/2000)
04/06/2000	25	Motion by Nitinol Medical Tech for leave to file reply , filed. (fmr) (Entered: 04/10/2000)
04/06/2000	26	Response by Nitinol Medical Tech in opposition to [23-1] motion for protective order and reply to defendants opposition to motion to compel, filed. (fmr) (Entered: 04/10/2000)
04/06/2000	27	Response by Nitinol Medical Tech in opposition to [20-1] motion to compel in accordance with the stipulated protective order , filed. (fmr) (Entered: 04/10/2000)
04/06/2000	28	SEALED Exhibits by Nitinol Medical Tech [27-1] opposition response (fmr) (Entered: 04/10/2000)
04/10/2000		Judge Nancy Gertner . Endorsed Order entered granting [25-1] motion for leave to file reply . [EOD Date 4/10/00] (fmr) (Entered: 04/10/2000)
04/14/2000	29	Judge Nancy Gertner . ORDER entered: referral . referred Mag. Judge Robert B. Collings : [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel . Purpose: ruling . (fmr) (Entered: 04/14/2000)
04/17/2000		Motion(s) no longer referred: [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel . (fmr) (Entered: 04/18/2000)
04/17/2000	30	Mag. Judge Robert B. Collings . ORDER entered: referral . referred Mag. Judge David M. Cohen : [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel . Purpose: determination . (fmr) (Entered: 04/18/2000)
05/01/2000	31	Motion by Aga Medical Corp. to stay all discovery and pretrial deadlines , filed. (fmr) (Entered: 05/02/2000)

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05/01/2000	32	Motion by Nitinol Medical Tech to extend time to to finish discovery , filed. (fmr) (Entered: 05/02/2000)
05/01/2000	38	Memorandum by Nitinol Medical Tech in support of [32-1] motion to extend time to to finish discovery , filed. (fmr) (Entered: 05/30/2000)
05/05/2000	33	Response by Aga Medical Corp. in opposition to [32-1] motion to extend time to to finish discovery , filed. (fmr) (Entered: 05/05/2000)
05/11/2000	35	Mag. Judge David M. Cohen . Clerk's Notes: re: preliminary teleconference. #23 m/supplemental protective order is denied. Further hearing to be set before Judge David Cohen on motions 14 and 20 (est 2-3hrs) Court Reporter: none (fmr) (Entered: 05/17/2000)
05/11/2000		Judge Nancy Gertner . Endorsed Order entered denying [23-1] motion for protective order . [EOD Date 5/17/00] (fmr) (Entered: 05/17/2000)
05/15/2000	34	Response by Nitinol Medical Tech in opposition to [31-1] motion to stay all discovery and pretial deadlines , filed. (fmr) (Entered: 05/16/2000)
05/17/2000		Tele-conference held . (fmr) (Entered: 05/17/2000)
05/17/2000	36	Motion by Aga Medical Corp. for leave to file reply , filed. (fmr) (Entered: 05/17/2000)
05/23/2000		Motion hearing re: [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel (fmr) (Entered: 05/30/2000)
05/23/2000	39	Mag. Judge David M. Cohen . Clerk's Notes: re: motion hearing granting in part, denying in part [20-1] motion to compel in accordance with the stipulated protective order Court Reporter: Terry (fmr) (Entered: 05/30/2000)
05/26/2000		Judge Nancy Gertner . Endorsed Order entered granting [36-1] motion for leave to file reply . [EOD Date 5/26/00] (fmr) (Entered: 05/26/2000)
05/26/2000	37	Reply/response by Aga Medical Corp. to [34-1] opposition response , filed. (fmr) (Entered: 05/26/2000)
05/30/2000		Motion(s) no longer referred: [20-1] motion to compel in accordance with the stipulated protective order . (fmr) (Entered: 05/30/2000)
06/02/2000	40	Expert report of Harry Manbeck (fmr) (Entered: 06/05/2000)
06/06/2000	41	Motion by Nitinol Medical Tech for leave to file reply , filed. (fmr) (Entered: 06/08/2000)
06/06/2000	48	Reply/response by Nitinol Medical Tech to opposition to extened pre trial deadlines, filed. (fmr) (Entered: 06/13/2000)
06/08/2000		Judge Nancy Gertner . Endorscd Order entered granting [41-1] motion for leave to file reply . Reply is attached to motion for leave [EOD Date 6/8/00] (fmr) (Entered: 06/08/2000)
06/09/2000	42	Motion by Aga Medical Corp. for leave to file brief in excess of 20 pgs. ,

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		filed. (fmr) (Entered: 06/09/2000)
06/09/2000		Judge Nancy Gertner . Endorsed Order entered granting [42-1] motion for leave to file brief in excess of 20 pgs. . [EOD Date 6/9/00] (fmr) (Entered: 06/09/2000)
06/09/2000	43	Motion by Aga Medical Corp. for summary judgment , filed. (fmr) (Entered: 06/09/2000)
06/09/2000	44	Memorandum by Aga Medical Corp. in support of [43-1] motion for summary judgment , filed. (fmr) (Entered: 06/09/2000)
06/09/2000	45	Affidavit of Paul T. Dietz , re: [44-1] support memorandum , filed. (fmr) (Entered: 06/09/2000)
06/09/2000	46	Motion by Aga Medical Corp. for sanctions , filed. (fmr) Modified on 06/09/2000 (Entered: 06/09/2000)
06/09/2000	47	Memorandum by Aga Medical Corp. in support of [46-1] motion for sanctions , filed. (fmr) (Entered: 06/09/2000)
06/20/2000	49	Motion by Aga Medical Corp. for leave to file reply , filed. (fmr) (Entered: 06/20/2000)
06/20/2000		Judge Nancy Gertner . Endorsed Order entered granting [49-1] motion for leave to file reply . [EOD Date 6/20/00] (fmr) (Entered: 06/20/2000)
06/20/2000	50	Response by Aga Medical Corp. in opposition to [48-1] reply , filed. (fmr) (Entered: 06/20/2000)
06/21/2000	51	Motion by Nitinol Medical Tech to extend time to 7/14/00 to respond to motion for s.j , filed. (fmr) (Entered: 06/22/2000)
06/22/2000	52	Response by Aga Medical Corp. in opposition to [51-1] motion to extend time to 7/14/00 to respond to motion for s.j , filed. (fmr) (Entered: 06/26/2000)
06/30/2000	53	Motion by Aga Medical Corp. under rule 41(b)to dismiss plaintiffs' claims , filed. c/s (fmr) (Entered: 07/06/2000)
07/10/2000	54	Status report by Nitinol Medical Tech regarding its motion to compel , filed. (fmr) (Entered: 07/10/2000)
07/10/2000	55	Motion by Aga Medical Corp. for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel , filed. (fmr) (Entered: 07/10/2000)
07/10/2000	56	Motion by Aga Medical Corp. to compel , filed. (fmr) (Entered: 07/10/2000)
07/10/2000	57	Memorandum by Aga Medical Corp. in support of [56-1] motion to compel , filed. (fmr) (Entered: 07/10/2000)
07/14/2000	58	Response by Aga Medical Corp. in opposition to [54-1] status report , filed. (fmr) (Entered: 07/18/2000)

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07/14/2000	59	Motion by Nitinol Medical Tech to seal/impound , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	60	Motion by Nitinol Medical Tech for leave to file brief exceeding pg limit , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	61	Memorandum by Nitinol Medical Tech in opposition to [43-1] motion for summary judgment , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	62	SEALED Affidavit , re: [61-1] opposition memorandum , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	63	Affidavit , re: [61-1] opposition memorandum , filed. (fmr) (Entered: 07/18/2000)
07/17/2000	64	Response by Nitinol Medical Tech in opposition to [46-1] motion for sanctions and to dismiss under rule 41(b), filed. c/s (fmr) (Entered: 07/19/2000)
07/18/2000		Judge Nancy Gertner . Endorsed Order entered granting [59-1] motion to seal/impound . [EOD Date 7/18/00] (fmr) (Entered: 07/18/2000)
07/18/2000		Judge Nancy Gertner . Endorsed Order entered granting [60-1] motion for leave to file brief exceeding pg limit . [EOD Date 7/18/00] (fmr) (Entered: 07/18/2000)
07/25/2000	65	Response by Nitinol Medical Tech in opposition to [56-1] motion to compel , filed. c/s (fmr) (Entered: 07/25/2000)
07/25/2000	66	Response by Nitinol Medical Tech in opposition to [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel , filed. (fmr) (Entered: 07/25/2000)
07/27/2000	67	Motion by Aga Medical Corp. for leave to file reply memorandum , filed. (fmr) (Entered: 08/01/2000)
08/01/2000	68	Response by Nitinol Medical Tech in opposition to [66-1] opposition response , filed. (fmr) (Entered: 08/01/2000)
08/04/2000	69	Motion by Aga Medical Corp. for leave to file reply brief , filed. (fmr) (Entered: 08/07/2000)
08/04/2000	70	SEALED Reply/response by Aga Medical Corp. to [66-1] opposition response , filed. (fmr) (Entered: 08/07/2000)
08/07/2000		Judge Nancy Gertner . Endorsed Order entered granting [69-1] motion for leave to file reply brief . [EOD Date 8/7/00] (fmr) (Entered: 08/07/2000)
08/09/2000	71	Judge Nancy Gertner . ORDER entered: referral . referred Mag. Judge Judith G. Dein : [56-1] motion to compel, [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel, [14-1] motion to compel . Purpose: ruling . (fmr) (Entered: 08/14/2000)

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08/21/2000		Terminated document: terminating [51-1] motion to extend time to 7/14/00 to respond to motion for s.j . Motion is moot, response has been filed (fmr) (Entered: 08/21/2000)
08/22/2000	74	Mag. Judge Robert B. Collings . Notice of Hearing/conference: Motion hearing before Mag. Judge Robert B. Collings set for 2:00 9/12/00 for [14-1] motion to compel . (fmr) (Entered: 08/25/2000)
08/23/2000	72	Motion by Aga Medical Corp. for leave to file reply memo , filed. (fmr) (Entered: 08/25/2000)
08/23/2000	73	Reply/response by Aga Medical Corp. to [64-1] opposition response , filed. (fmr) (Entered: 08/25/2000)
08/25/2000		Judge Nancy Gertner . Endorsed Order entered granting [72-1] motion for leave to file reply memo . [EOD Date 8/25/00] (fmr) (Entered: 08/25/2000)
08/28/2000		Judge Nancy Gertner . Endorsed Order entered denying [53-1] motion under rule 41(b)to dismiss plaintiffs' claims . [EOD Date 8/30/00] (fmr) (Entered: 08/30/2000)
08/28/2000		Judge Nancy Gertner . Endorsed Order entered mootng [51-1] motion to extend time to 7/14/00 to respond to motion for s.j . [EOD Date 8/30/00] (fmr) (Entered: 08/30/2000)
09/06/2000		Judge Nancy Gertner . Endorsed Order entered granting [67-1] motion for leave to file reply memorandum . [EOD Date 9/6/00] (mcm) (Entered: 09/06/2000)
09/13/2000		Motion hearing re: [56-1] motion to compel, [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel (fmr) (Entered: 09/18/2000)
09/13/2000	75	Mag. Judge Judith G. Dein . Clerk's Notes: re: motion hearing held on dates 9/13, by 9/21/00 responses due, 9/28/00 parties status report regarding interogs, 9/29/00 plts memo on privilege, 10/10/00 plts shall produce any docs to modified request Court Reporter: Tape (fmr) (Entered: 09/18/2000)
09/14/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [14-1] motion to compel . See order [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/14/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [56-1] motion to compel . See order [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/14/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel . [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/14/2000	76	Mag. Judge Judith G. Dein . Order entered granting in part, denying in

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		part [14-1] motion to compel granting in part, denying in part [56-1] motion to compel . [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/29/2000	77	Supplemental Memorandum by Nitinol Medical Tech in support of [14-1] motion to compel , pursuant to order issued by Mag Dein filed. (fmr) (Entered: 10/03/2000)
10/10/2000	78	Status report on discovery by Nitinol Medical Tech, Aga Medical Corp. , filed. (fmr) (Entered: 10/10/2000)
10/13/2000	79	Motion by Aga Medical Corp. to bifurcate trial , filed. (fmr) (Entered: 10/13/2000)
10/13/2000	80	Response by Aga Medical Corp. in opposition to [73-1] reply , filed. (fmr) (Entered: 10/13/2000)
10/16/2000		Tele-conference held . (fmr) (Entered: 10/17/2000)
10/16/2000	81	Mag. Judge Judith G. Dein . Clerk's Notes: re: discovery issues. Court hears from the parties and will issue an order Court Reporter: Tape (fmr) (Entered: 10/17/2000)
10/17/2000	83	Mag. Judge Judith G. Dein . Supplemental Order on Motion to compel entered . [EOD Date 10/23/00] (fmr) (Entered: 10/23/2000)
10/18/2000	82	Mag. Judge Judith G. Dein . Notice of Hearing/conference: Motion hearing before Mag. Judge Judith G. Dein set for 10:00 10/31/00 for [32-1] motion to extend time to to finish discovery, set for 10:00 10/31/00 for [31-1] motion to stay all discovery and pretial deadlines . (fmr) (Entered: 10/18/2000)
10/26/2000	84	Mag. Judge Judith G. Dein . Supplemental Memorandum and Order on motion to compel regarding waiver of atty- client privilege entered. [EOD Date 10/26/00] (fmr) (Entered: 10/26/2000)
10/30/2000	85	Memorandum by Nitinol Medical Tech in opposition to [79-1] motion to bifurcate trial , filed. (fmr) (Entered: 11/01/2000)
10/31/2000	86	Mag. Judge Judith G. Dein . Order entered denying [31-1] motion to stay all discovery and pretial deadlines granting in part, denying in part [32-1] motion to extend time to to finish discovery . [EOD Date 11/6/00] (fmr) (Entered: 11/06/2000)
10/31/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [32-1] motion to extend time to to finish discovery . Extended discovery schedule to be set at a later date [EOD Date 11/6/00] (fmr) (Entered: 11/06/2000)
10/31/2000		Mag. Judge Judith G. Dein . Endorsed Order entered denying [31-1] motion to stay all discovery and pretial deadlines, after hearing . [EOD Date 11/6/00] (fmr) (Entered: 11/06/2000)
11/01/2000		Motion to bifurcate sent to chambers with oppositon (fmr) (Entered: 11/01/2000)

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11/03/2000	89	Statement of counsel filed by Aga Medical Corp. , Re: position statement. (fmr) (Entered: 11/09/2000)
11/07/2000	87	Statement of counsel filed by Nitinol Medical Tech , Re: prior art. (fmr) (Entered: 11/08/2000)
11/08/2000	88	Mag. Judge Judith G. Dein . Order entered, amending [84-1] memorandum order . [EOD Date 11/9/00] (fmr) (Entered: 11/09/2000)
11/09/2000	90	Notice of change of address filed by Thomas C. O'Konski by Aga Medical Corp. . (fmr) (Entered: 11/09/2000)
11/15/2000	91	Status report by Nitinol Medical Tech , filed. (fmr) (Entered: 11/20/2000)
11/15/2000	92	Affidavit , re: [91-1] status report , filed. (fmr) (Entered: 11/20/2000)
11/15/2000	93	Affidavit , re: [91-1] status report , filed. (fmr) (Entered: 11/20/2000)
11/21/2000	95	Motion by Aga Medical Corp. for protective order , filed. (fmr) (Entered: 11/28/2000)
11/22/2000	94	Mag. Judge Judith G. Dein . Order entered, compelling production of discovery and discovery schedule . [EOD Date 11/28/00] (fmr) (Entered: 11/28/2000)
12/01/2000	96	Motion by Nitinol Medical Tech to extend time to no date given to respond to motion to compel , filed. (fmr) (Entered: 12/06/2000)
12/01/2000	97	Response by Nitinol Medical Tech in opposition to [95-1] motion for protective order , filed. (fmr) (Entered: 12/06/2000)
12/06/2000	98	Statement of counsel filed by Nitinol Medical Tech , Re: discovery. (fmr) (Entered: 12/06/2000)
12/06/2000	99	Statement of counsel filed by Aga Medical Corp. , Re: proposed discovery schedule. (fmr) (Entered: 12/06/2000)
12/07/2000	100	Statement of counsel filed by Nitinol Medical Tech , Re: discovery schedule. (fmr) (Entered: 12/07/2000)
12/07/2000	101	Mag. Judge Judith G. Dein . Order entered granting in part, denying in part [95-1] motion for protective order . [EOD Date 12/7/00] (fmr) (Entered: 12/07/2000)
12/07/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting [96-1] motion to extend time to no date given to respond to motion to compel . [EOD Date 12/7/00] (fmr) (Entered: 12/07/2000)
12/07/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [95-1] motion for protective order . [EOD Date 12/7/00] (fmr) (Entered: 12/07/2000)
12/15/2000	102	FAXED Letter by Paul T. Dietz dated: 12/15/00 to: Judge Dein re: proposed order filed. (fmr) (Entered: 12/22/2000)
12/20/2000	104	Letter dated: 12/20/00 to: Tom re: fax of proposed order filed. (fmr)

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		(Entered: 12/26/2000)
12/21/2000	103	Mag. Judge Judith G. Dein . Order entered . [EOD Date 12/26/00] (fmr) (Entered: 12/26/2000)
01/16/2001	105	Judge Nancy Gertner . Notice of Hearing/conference: set status conference for 2:30 2/1/01 . (fmr) (Entered: 01/17/2001)
01/24/2001	106	Motion by Aga Medical Corp. for summary judgment , filed. (fmr) (Entered: 01/24/2001)
01/24/2001	107	Motion by Aga Medical Corp. for sanctions , filed. (fmr) (Entered: 01/24/2001)
01/24/2001	108	Memorandum by Aga Medical Corp. in support of [107-1] motion for sanctions , filed. (fmr) (Entered: 01/24/2001)
01/24/2001		Judge Nancy Gertner . Endorsed Order entered denying [46-1] motion for sanctions, at this time . [EOD Date 1/25/01] (fmr) (Entered: 01/25/2001)
01/24/2001		Judge Nancy Gertner . Endorsed Order entered denying [43-1] motion for summary judgment . [EOD Date 1/25/01] (fmr) (Entered: 01/25/2001)
01/24/2001		Judge Nancy Gertner . Endorsed Order entered denying [79-1] motion to bifurcate trial . [EOD Date 1/25/01] (fmr) (Entered: 01/25/2001)
02/01/2001		Status conference held . (fmr) (Entered: 02/06/2001)
02/01/2001	109	Judge Nancy Gertner . Clerk's Notes: re: status conference . plt request a stay, dft object. Judge adopts J Deins 12/21/00 order. Pltff will file an opposition to summary judgment and an assetned to motion for stay on or before 2/16/01. Trial anticipated for around 12/01 Court Reporter: none (fmr) (Entered: 02/06/2001)
02/20/2001	110	Motion by Nitinol Medical Tech to stay , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	111	Response by Nitinol Medical Tech in opposition to [106-1] motion for summary judgment , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	111	Memorandum by Nitinol Medical Tech in support of [110-1] motion to stay , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	112	Affidavit of Lloyd Marks , re: [111-1] support memorandum, [111-1] opposition response , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	113	Affidavit of Morris Simon , re: [111-1] support memorandum, [111-1] opposition response , filed. (fmr) (Entered: 02/20/2001)
03/02/2001	114	Memorandum by Aga Medical Corp. in opposition to [110-1] motion to stay , filed. (fmr) (Entered: 03/02/2001)
03/02/2001	115	Motion by Aga Medical Corp. for leave to file reply memo , filed. (fmr) (Entered: 03/02/2001)
03/02/2001		Motion for leave #115 sent to chambers with proposed filing (fmr)

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		(Entered: 03/02/2001)
03/02/2001		Motion to stay #114 and motion for summary judgment #106 sent to chambers for ruling with oppositions (fmr) (Entered: 03/02/2001)
03/29/2001	116	Motion by Nitinol Medical Tech for leave to file reply to opposition , filed. (fmr) (Entered: 03/29/2001)
03/29/2001		Motion for leave # 116 and proposed filing sent to chambers (fmr) (Entered: 03/29/2001)
04/10/2001	117	Response by Aga Medical Corp. in opposition to [116-1] motion for leave to file reply to opposition , filed. (eaf) (Entered: 04/10/2001)
04/10/2001		Status conference set at 2:00 4/25/01 before Judge Nancy Gertner. All parties notified by telephone on 4/10/01. (mcm) (Entered: 04/10/2001)
04/25/2001		Motion hearing re: [110-1] motion to stay. (eaf) (Entered: 04/26/2001)
04/25/2001	118	Judge Nancy Gertner . Clerk's Notes: re: motion to stay, set status conference for 2:30 10/10/01 Will draft stay order. Stay contingent on reexamination being prosecuted expeditiously. Motions not termed; case closed administratively pending reprosecution of patent. (eaf) (Entered: 04/26/2001)
04/25/2001	119	Judge Nancy Gertner . Order entered granting [110-1] motion to stay . [EOD Date 4/26/01] (eaf) (Entered: 04/26/2001)
04/26/2001		CASE NO LONGER REFERRED TO . (eaf) (Entered: 04/26/2001)
04/26/2001		Motion(s) no longer referred: [116-1] motion for leave to file reply to opposition, [115-1] motion for leave to file reply memo, [110-1] motion to stay, [107-1] motion for sanctions, [106-1] motion for summary judgment, [96-1] motion to extend time to no date given to respond to motion to compel, [95-1] motion for protective order, [79-1] motion to bifurcate trial, [72-1] motion for leave to file reply memo, [69-1] motion for leave to file reply brief, [67-1] motion for leave to file reply memorandum, [60-1] motion for leave to file brief exceeding pg limit, [59-1] motion to seal/impound, [56-1] motion to compel, [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel, [53-1] motion under rule 41(b) to dismiss plaintiffs' claims, [51-1] motion to extend time to 7/14/00 to respond to motion for s.j, [49-1] motion for leave to file reply, [46-1] motion for sanctions, [43-1] motion for summary judgment, [42-1] motion for leave to file brief in excess of 20 pgs., [41-1] motion for leave to file reply, [36-1] motion for leave to file reply, [32-1] motion to extend time to to finish discovery, [31-1] motion to stay all discovery and pretrial deadlines, [25-1] motion for leave to file reply, [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [17-1] motion for leave to file reply memorandum, [16-1] motion to extend time to no date given to file opposition, [14-1] motion to compel, [13-1] joint motion to modify discovery schedule, [5-1] motion for Paul Dietz to appear pro hac vice fee status: pd fee amt: 50.00 Receipt #:

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		14215 . (caf) (Entered: 04/26/2001)
04/26/2001		Case closed. (caf) (Entered: 04/26/2001)
10/02/2001	120	Consented to Motion by Aga Medical Corp. for James T. Nikolai to appear pro hac vice fee status: pd fee amt: \$50.00 Receipt #: 34179 , filed. c/s. (jf) (Entered: 10/03/2001)
10/02/2001	121	Certificate of Good Standing by Attorney James T. Nikolai, filed. (jf) (Entered: 10/03/2001)
10/03/2001		Judge Nancy Gertner . Endorsed Order entered granting [120-1] motion for James T. Nikolai to appear pro hac vice fee status: pd fee amt: \$50.00 Receipt #: 34179 Added James T. Nikolai. cc:cl. [EOD Date 10/3/01] (jf) (Entered: 10/03/2001)
10/10/2001		Status conference held . (jl) (Entered: 10/11/2001)
10/10/2001	122	Judge Nancy Gertner . Clerk's Notes: re: Telephone Conference Held., Set status conference for 3:00 4/30/02 , by telephone if requested. Stayed continued until 4/30/02 by the consent of all parties. Court Reporter: None (jl) (Entered: 10/11/2001)
05/02/2002	123	Judge Nancy Gertner . Clerk's Notes: re: Telephone Conference Held; ORDERED: Case stayed until 10/31/02; parties in agreement that case is Administratively closed until patent office issues an opinion on outstanding claims. Judge Gertner will consider dismissing(w/out prejudice) case if the patent office delays issuing their decision past 2002, Set status conference for 2:30 10/31/02 Court Reporter: None (jf) (Entered: 05/14/2002)
10/31/2002		Telephone/Status conference held. (jf) (Entered: 11/01/2002)
10/31/2002	124	Judge Nancy Gertner. Clerk's Notes: re: Telephone Conference Held; Set status conference for 2:15 2/26/02 (jf) (Entered: 11/01/2002)
02/27/2003	125	Judge Nancy Gertner. Notice of Hearing/conference: Set telephone status conference for 2:15 3/18/03 . Notice mailed to counsel. (jf) (Entered: 02/28/2003)
03/18/2003		Telephone conference held. (jf) (Entered: 03/19/2003)
03/18/2003	126	Judge Nancy Gertner . Clerk's Notes: re: telephone conference held; case stayed for 60 days; counsel will submit a proposed order forthwith. Court Reporter: none (jf) (Entered: 03/19/2003)
09/30/2003	127	Letter (non-motion) from Thomas C. O'Konski to Judge Gertner re: patent-in-suit before the US Patent and Trademark Office, filed. (sent to chambers) (Filo, Jennifer) (Entered: 10/06/2003)
10/03/2003	128	Letter/request (non-motion) from Dominic E. Massa to Judge Gertner re: Letter dated 9/30/03 by Thomas C. O'Konski, filed. (sent to chambers w/#127) (Filo, Jennifer) (Entered: 10/06/2003)
10/16/2003		Electronic Clerk's Notes for proceedings held before Judge Nancy

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		Gertner : TELEPHONE CONFERENCE HELD, parties report status of case. Ordered: judge will reconsider dft's motion to dismiss, matters taken under advisement.. (Court Reporter none.) (Molloy, Maryellen) (Entered: 10/16/2003)
12/01/2003	<u>129</u>	Judge Nancy Gertner : ORDER OF DISMISSAL entered (Filo, Jennifer) (Entered: 12/02/2003)

PACER Service Center			
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02/08/2005 10:14:01			
<b>PACER Login:</b>	nm0073	<b>Client Code:</b>	aga
<b>Description:</b>	Docket Report	<b>Search Criteria:</b>	1:98-cv-12506-NG
<b>Billable Pages:</b>	8	<b>Cost:</b>	0.64

**EXHIBIT L**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT COURT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, )  
INC. and LLOYD A. MARKS, )  
Plaintiffs, )  
v. )  
AGA MEDICAL CORPORATION, )  
Defendant. )  
GERTNER, D.J.

Civ. No. 98-12506-NG

DOCKETED

ORDER RE: MOTION TO STAY  
April 25, 2001

3  
This action concerns United States Patent No. 5,105,420 ("the Marks patent"), which claims a new "aperture occlusion device" used to block the flow of blood through an opening between cavities in a human body. The plaintiffs, Nitinol Medical Technologies and Lloyd A. Marks ("Nitinol"), allege that defendant's products infringe one or more claims of the Marks patent. The defendant, AGA Medical Corporation ("AGA"), counters that the Marks patent is invalid in view of prior art.

One issue is not in dispute, however: The parties apparently agree that two pieces of purported prior art were not before the Patent Office ("PTO") when the Marks patent was originally prosecuted. To rectify this situation, Nitinol now seeks a stay of this action pending PTO reexamination of the Marks patent.

I agree with Nitinol that a stay will save both the parties' and the Court's resources, particularly as (1) many of the issues raised in this case (such as anticipation by prior art) may well be resolved by reexamination, (2) if I were to resolve any issues

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at this time, the parties would likely have to relitigate some of the same issues following reexamination of the patent, and (3) although this case is several years old, document discovery is not yet complete, and deposition discovery has not begun. Accordingly, the plaintiffs' motion to stay this action pending reexamination of the Marks patent by the PTO [docket entry #110] is **ALLOWED**.

AGA is understandably concerned about this stay, as it could ultimately be found liable for infringement of the Marks patent during the period of the stay. In response to this concern, I note the following:

1. Claims amended during reexamination are only "entitled to the date of the original patent if they are without substantive change or are legally 'identical' to the claims in the original patent." Tennant Co. v. Hako Minuteman, Inc., 878 F.2d 1413, 1417 (Fed. Cir. 1989) (citing 35 U.S.C. § 307(b)).
2. Even if this Court ultimately determines that (1) the reexamined Marks patent claims are entitled to the date of the original patent, and (2) AGA is liable for infringement of the Marks patent during the period of the stay, it may still "be appropriate to limit prejudgment interest, or perhaps even deny it altogether," if I find the plaintiffs responsible for "undue delay in prosecuting [this] lawsuit." Allen Archery, Inc. v. Browning Manufacturing Co., 898 F.2d 787, 791 (Fed. Cir. 1990).

To further address AGA's concerns, I will continue to meet with the parties regularly during the stay, first to ensure that Nitinol moves expeditiously to obtain PTO reexamination of the Marks patent, and then to monitor the status of the reexamination process. To this end, a status conference is scheduled for Wednesday, October 10, 2001, at 2:30 p.m.

SO ORDERED.

Dated: April 25, 2001



---

NANCY GERTNER, U.S.D.J.

**EXHIBIT M**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL LABORATORIES,	)	
INC. ET AL.	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 98-12506-NG
	)	
AGA MEDICAL CORPORATION,	)	
<u>Defendant.</u>	)	
GERTNER, D.J.:		

ORDER OF DISMISSAL

December 1, 2003

The Defendant in this case moves to dismiss the Plaintiffs' Complaint in its letter dated September 30, 2003. [Document # 127]. The Defendant's request is **GRANTED**. The case is thus **DISMISSED** without prejudice.

SO ORDERED.

Dated: December 1, 2003

s/Nancy Gertner

NANCY GERTNER, U.S.D.J.

**EXHIBIT N - Part 1**



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

REEXAM CONTROL NUMBER	FILING DATE	PATENT NUMBER
90/006,043	06/25/2001	5,108,420

CONFIRMATION NO.

002779

BLANK ROME COMISKY & MCCAULEY LLP  
THE FARRAGUT BUILDING SUITE 1000  
900 17TH STREET NW  
WASHINGTON, DC 20006

Date Mailed: 06/28/2001

## NOTICE OF REEXAMINATION REQUEST FILING DATE

(Patent Owner Requester)

Requester is hereby notified that the filing date of the request for reexamination is 06/25/2001, the date the required fee of \$2,520 was received. (See CFR 1.510(d)).

A decision on the request for reexamination will be mailed within three months from the filing date of the request for reexamination. (See 37 CFR 1.515(a)).

Pursuant to 37 CFR 1.33(c), future correspondence in this reexamination proceeding will be with the latest attorney or agent of the record in the patent file.

The paragraphs checked below are part of this communication:

- ☐ 1. The party receiving the courtesy copy is the latest attorney or agent of record in the patent file.
- ☐ 2. The person named to receive the correspondence in this proceeding has not been made the latest attorney or agent of record in the patent file because:
  - ☐ A. Requester's claim of ownership of the patent is not verified by the record.
  - ☐ B. The request papers are not signed with a real or apparent binding signature.
  - ☐ C. The mere naming of a correspondence addressee does not result in that person being appointed as the latest attorney or agent of record in the patent file.
- ☒ 3. Addressee is the latest attorney or agent of record in the patent file.
- ☐ 4. Other \_\_\_\_\_

*M. A. Smith*  
Office of Patent Legal Administration  
Central Reexamination Unit (703) 308-9692

PART 2 - OFFICE COPY



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

REEXAM CONTROL NUMBER	FILING DATE	PATENT NUMBER
90/006,043	06/25/2001	5108420

002779  
BLANK ROME COMISKY & MCCAULEY LLP  
THE FARRAGUT BUILDING SUITE 1000  
900 17TH STREET NW  
WASHINGTON, DC 20006

CONFIRMATION NO.  
REEXAM ASSIGNMENT NOTICE

Date Mailed: 06/28/2001

## NOTICE OF ASSIGNMENT OF REEXAMINATION REQUEST

The above-identified request for reexamination has been assigned to Art Unit 3731. All future correspondence to the proceeding should be identified by the control number listed above and directed to the assigned Art Unit.

A copy of this Notice is being sent to the latest attorney or agent of record in the patent file or to all owners of record. (See 37 CFR 1.33(c)). If the addressee is not, or does not represent, the current owner, he or she is required to forward all communications regarding this proceeding to the current owner(s). An attorney or agent receiving this communication who does not represent the current owner(s) may wish to seek to withdraw pursuant to 37 CFR 1.36 in order to avoid receiving future communications. If the address of the current owner(s) is unknown, this communication should be returned within the request to withdraw pursuant to Section 1.36.

*[Signature]*  
Office of Patent Legal Administration  
Central Reexamination Unit (703) 308-9692

PART 2 - OFFICE COPY



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
98/006,040	06/25/01	5,100,000	000 36-5, 000002

000779  
BLAND BOMB COMPANY & HODGKINLEY LLP  
THE PARRAGUT BUILDING SUITE 1000  
900 17TH STREET NW  
WASHINGTON DC 20006

EXAMINER	ART UNIT	PAPER NUMBER
THOMAS L. H.		

DATE MAILED: 03/21/01

## ORDER GRANTING/DENYING REQUEST FOR REEXAMINATION

The request for reexamination has been considered. Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s): ☐ PTO-892, ☒ PTO-1449, ☐ Other: \_\_\_\_\_

☒ The request for reexamination is GRANTED.

RESPONSE TIMES ARE SET TO EXPIRE AS FOLLOWS:

For Patent Owner's Statement (optional): TWO MONTHS from the mailing date hereof. 37 CFR 1.530(b).  
**EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's reply (optional): TWO MONTHS from the date of service of any patent owner's statement. 37 CFR 1.535. **NO EXTENSION OF TIME IS PERMITTED.** If patent owner does not file a timely statement under 37 C.F.R. 1.530(b), no reply by requester is permitted.

2. ☐ The request for reexamination is DENIED.

This decision is not appealable. 35 U.S.C. 303(c). Requester may seek review by petition to the Commissioner within ONE MONTH from the mailing date hereof. 37 CFR 1.515(c). **EXTENSIONS OF TIME ONLY UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26(c) will be made to requester (listed below if not patent owner)  
☐ by Treasury check, ☐ by credit to Deposit Account No. \_\_\_\_\_  
unless notified otherwise. 35 U.S.C. 303(c).

(Third party requester's correspondence address)

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A substantial new question of patentability affecting claims 1-14 of United States Patent Number 5,108,420 is raised by the request for reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in reexamination proceedings are provided for in 37 CFR 1.550(c).

Requestor cites Kamiya (U.S. Patent No. 5,192,301) and German Publication DD 233 303 A1. These documents are not of record in the prosecution file of Patent Number 5,108,420 to Marks. The request indicates that Requestor believes that a substantial new question of patentability exists with respect to at least one claim of the Marks Patent in view of these two documents. Each of these documents teaches using a plug device adapted to occlude an aperture within a body surface wherein the plug passes through the aperture and includes portions which are urged toward one another to occlude the aperture. Further, each document teaches forming at least one shape memory element as part of the plug. The new teaching of each of these two documents is relevant to claims 1-14 of the Marks patent. The new teaching was not previously considered nor addressed in the prior examination of the patent or

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Page 3

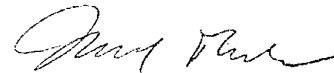
Art Unit: 3731

a final holding of invalidity by the Federal Courts. A reasonable examiner would consider the new teaching to be important in deciding to allow the claims being considered. Therefore, a substantial new question of patentability affecting claims 1-14 of the Marks patent is raised by the request and claims 1-14 will be reexamined.

Requestor is reminded of the affirmative duty to inform the examiner of the existence of any litigation involving the patent as well as changes in the status of such litigation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981.

mht  
August 17, 2001



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731


**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	JUNE 25, 2001	5,108,420	000365.00002

002779

BLANK ROME COMISKY & MCCAULEY LLP  
 THE FARRAGUT BUILDING, SUITE 1000  
 900 17<sup>TH</sup> STREET NW  
 WASHINGTON DC 20006

EXAMINER

THALER, M.

ART UNIT

PAPER

3731

9

DATE MAILED: FEBRUARY 20, 2002 *HC*

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED - PATENT  
 2002 FEB 20 10 20 AM

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark OfficeAddress: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	6/25/01	5,108,420	

EXAMINER	
THALER, M.	
ART UNIT	PAPER NUMBER
3731	9
DATE MAILED: 2/20/02	

## OFFICE ACTION IN REEXAMINATION

☒ Responsive to the communication(s) filed on OCT. 18, 2001. ☐ This action is made FINAL.

A shortened statutory period for response to this action is set to expire TWO month(s) from the date of this letter. Failure to respond within the period for response will cause termination of the proceeding and issuance of a reexamination certificate in accordance with this action. 37 CFR 1.550(d). EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).

## PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-992. 3. ☐ Notice of Informal Patent Drawing, PTO-948.  
2. ☒ Information Disclosure Citation, PTO-1449. 4. ☐

## PART II SUMMARY OF ACTION:

1. ☒ Claims 1-33 are subject to reexamination.  
2. ☐ Claims are not subject to reexamination.  
3. ☐ Claims have been cancelled.  
4. ☐ Claims are confirmed.  
5. ☐ Claims are patentable.  
6. ☒ Claims 1-33 are rejected.  
7. ☐ Claims are objected to.  
8. ☐ The formal drawings filed on are acceptable.  
9. ☐ The drawing correction request filed on is ☐ approved, ☐ disapproved.  
10. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received, ☐ not been received, ☐ been filed in Serial No. filed on.  
11. ☐ Since the proceeding appears to be in condition for issuance of a reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 435 O.G. 213.  
12. ☐ Other

cc: Requester

PTOL-466 (2-90)

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Claims 15-17 and 23-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 is inaccurate and/or confusing in that it defines a plurality of wires in line 1. Claim 1, from which claim 15 depends, defines a wire (singular) in line 4, which includes wire segments, one on each side of the aperture (lines 7-8). Thus, only one wire having wire segments exists. Claims 23, 25, 28 and 30 each have a similar problem. In claim 28, line 5, "occlusion-forming wire segments" should be "an occlusion-forming wire segment" since only one wire segment is on each side of the aperture.

Claims 18, 22, 24, 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 is limited to the embodiment of figures 6-9 since the embodiment of figures 1-5 fails to include helical coils as defined in claim 9, line 12. The original disclosure fails to disclose a membrane in the embodiment of figures 6-9. In fact, it is unclear how one could even include a membrane in this embodiment due to the manner in which helices 62a and 62b are deployed as explained in col.5, lines 38-68. Thus, there is no basis in the

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original disclosure for the membrane defined in claims 18, 22, 24, 29 and 33, each of which depends from a claim which is limited to the embodiment of figures 6-9.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9, 11, 14, 15, 18, 19, 21, 23-25, 27-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303). Munster shows a device 1 (either the embodiment of figure 1 or the embodiment of figure 2) to occlude an aperture within a body surface comprising a wire having an elongated configuration (the stretched form of the wire while it is in catheter 4 as seen in figure 3, for example and described on page 8, paragraph f and page 12, lines 3-9) and a preprogrammed configuration which includes occlusion-forming wire segments, one

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on each side of the aperture, urged toward one another. The wire segments are "urged toward one another" since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. The wire segments are inherently "occlusion-forming" since they are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Although the formation of the occlusion may be supplemented by the swellable plastic or the balloon described on page 9, paragraph j, the wire segments themselves are inherently "occlusion-forming" since they come to rest against the tissue on both sides of the aperture and therefore form a blockage for the blood. Even if this blockage is not perfect, i.e. even if some leakage occurs, the wire segments are still "occlusion-forming" since the occlusion is still formed even though it is not perfect. In any event, assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed

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position. Alternatively, the Munster wire segments are obviously "occlusion-forming" for the reasons set forth above. As to claims 4, 18 and 24, Munster shows foldable membranes (opposite end portions of the balloon described on page 10, lines 23-25). It is clear that the Munster balloon is long enough such that it extends as far as the wire segments on opposite sides of the aperture (at end portions 2 and 3 of the occluding device 1) so that the end portions of the balloon are "associated with" the wire segments on opposite sides of the aperture, as claimed. This is because the central portion of the balloon possesses a narrowed waist which is located around the central bridge or narrowed waist 5 of the occluding device 1, leaving the end portions of the balloon (on opposites ends of the narrowed waist) located at end portions 2 and 3 of the occluding device 1.

Claims 6, 10, 16, 17, 20, 22, 26, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303). As to claims 6, 16, 20, 26 and 31, Munster fails to show nitinol as the temperature responsive material. However, nitinol is well known in the art as being a material which is very responsive to temperature change. It would have been obvious to use nitinol as the Munster temperature responsive material for this reason. As to claims 10, 20, 26 and 31, Munster fails to show spring steel as the shape memory retentive material. However, spring steel is well known in the art as being a material which

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returns to its shape effectively. It would have been obvious to use as spring steel the Munster shape memory retentive material for this reason.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303) in view of Kamiya et al. (5,192,301). As to claims 1, 9 and 28, assuming *arguendo* that the Munster wire segments themselves are not "occlusion-forming", Kamiya et al. teach that the flange portions of a temperature responsive plug which are on opposite sides of the aperture which is to be occluded should be themselves "occlusion-forming" in order to form an effective seal (col. 3, lines 56-60 and figures 10a and 10b for example). It would have been obvious to make the Munster wire segments on opposite sides of the aperture "occlusion-forming" in order to reduce or eliminate any leakage of blood in view of this teaching. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious in view of the Kamiya et al. teaching of so coating the occluding member apparently for this reason (col. 7, lines 22-28). As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since Kamiya et al. teach that such defects may be corrected by an occluding device (col. 1, lines 15-18).

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The arguments in Patent Owner's Statement filed Oct. 18, 2001 as well as the declaration of Morris Simon, MD have been fully considered but they are not persuasive. Their allegation that Munster lacks any suggestion that there should be wire segments on either side of the device that "urge toward one another" and thereby create a tight seal around the defect (pages 5-7 of the Patent Owner's Statement) is not persuasive. The Munster wire segments are clearly urged toward one another since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. Thus, there is a biasing force which urges the Munster wire segments toward one another. Further, the wire segments are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Therefore they are inherently "occlusion-forming". Further, it should be noted that although Kamiya et al. was not used as a primary reference against the claims in this Office Action in order to avoid making numerous multiple rejections against the claims, the Kamiya et al. device is considered to include a "wire" since it is thin and elongated as seen in figure 16, for example. Thus, Kamiya et al. discloses all of the limitations in many of the claims.

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In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents **must** be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, which will be strictly enforced.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

20020219 14:00:00

mht  
February 19, 2002  
FAX (703) 305-3590



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731


**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	APRIL 28, 2001	5,108,420	000365.00002

BLANK ROME COMISKY & MCCAULEY, LLP  
 900 17<sup>TH</sup> STREET, N. W., SUITE 1000  
 WASHINGTON DC 20006

EXAMINER

THALER, M.

ART UNIT

PAPER

3731

17

DATE MAILED: SEPTEMBER 30, 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

90006043.071702

Commissioner of Patents and Trademarks


**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

 Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
 Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT PAPER NUMBER

17

DATE MAILED:

**OFFICE ACTION IN REEXAMINATION**
☒ Responsive to the communication(s) filed on JUNE 20, 2002 ☐ This action is made FINAL.

 A shortened statutory period for response to this action is set to expire ONE month(s) from the date of this letter. Failure to respond within the period for response will cause termination of the proceeding and issuance of a reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**
**PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.      | 3. <input type="checkbox"/> Notice of Informal Patent Drawing, PTO-948. |
| 2. <input checked="" type="checkbox"/> Information Disclosure Citation, PTO-1449. | 4. <input type="checkbox"/> _____                                       |

**PART II SUMMARY OF ACTION:**

- 2002-06-20
1. ☒ Claims 1-46 are subject to reexamination.
  2. ☐ Claims \_\_\_\_\_ are not subject to reexamination.
  3. ☐ Claims \_\_\_\_\_ have been cancelled.
  4. ☐ Claims \_\_\_\_\_ are confirmed.
  5. ☐ Claims \_\_\_\_\_ are patentable.
  6. ☒ Claims 1-46 are rejected.
  7. ☐ Claims \_\_\_\_\_ are objected to.
  8. ☐ The formal drawings filed on \_\_\_\_\_ are acceptable.
  9. ☐ The drawing correction request filed on \_\_\_\_\_ is ☐ approved, ☐ disapproved.
  10. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received, ☐ not been received, ☐ been filed in Serial No. \_\_\_\_\_ filed on \_\_\_\_\_.
  11. ☐ Since the proceeding appears to be in condition for issuance of a reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 435 O.G. 213.
  12. ☐ Other

cc: Requester

PTOL-406 (2-90)

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The drawing correction request filed on June 20, 2002 is approved.

The disclosure is objected to because of the following informalities: Reference numeral 23' is absent from the drawings. In figure 4, reference numeral 23 should be 23' and reference numeral 21a should be 21b. With these changes, reference numeral 23 would be absent from the drawings. Therefore, reference numeral 23 should be added to the drawings to denote the proper element or it should be deleted from the specification. The text in col. 5, lines 7-11 should be corrected to reflect these changes. Appropriate correction is required.

Claims 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 28, line 5, "occlusion-forming wire segments" should be "an occlusion-forming wire segment" since each wire has only one wire segment on each side of the aperture.

Claims 18 and 22-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 is limited to the embodiment of figures 6-9 since the embodiments of figures 1-5 fails to include helical coils as

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defined in claim 9, line 12. The original disclosure fails to disclose a membrane in the embodiment of figures 6-9. In fact, it is unclear how one could even include a membrane in this embodiment due to the manner in which helixes 62a and 62b are deployed as explained in col.5, lines 38-68. Thus, there is no basis in the original disclosure for the membrane defined in claims 18, 22, 24, 29 and 33, each of which depends from a claim (claim 9) which is limited to the embodiment of figures 6-9. Further, claims 23 and 25, which also depend from claim 9, each define more than one wire. The only embodiments which include more than one wire are the embodiments of figures 1-5. The original disclosure fails to disclose a plurality of wires in the embodiment of figures 6-9. Thus, there is no basis in the original disclosure for the plurality of wires defined in claims 23 and 25, each of which depends from a claim (claim 9) which is limited to the embodiment of figures 6-9. Claim 28 is similarly defective since it includes both a plurality of wires and helical coils.

Claims 1-5, 9, 11, 14, 15, 18, 19, 21, 23-25, 27-30, 32, 34-39, 41-44 and 46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Munster (Germany 233,303). Munster shows a device 1 (either the embodiment of figure 1 or the embodiment of figure 2) to occlude an aperture within a body surface comprising a wire having an elongated configuration (the stretched form of the wire while it is

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in catheter 4 as seen in figure 3, for example and described on page 8, paragraph f and page 12, lines 3-9) and a preprogrammed configuration which includes occlusion-forming wire segments, one on each side of the aperture, urged toward one another. The wire segments have been "urged toward one another" since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. The wire segments are inherently "occlusion-forming" since they are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Although the formation of the occlusion may be supplemented by the swelling plastic or the balloon described on page 9, paragraph j, the wire segments themselves are inherently "occlusion-forming" since they come to rest against the tissue on both sides of the aperture and therefore form a blockage for the blood. Even if this blockage is not perfect, i.e. even if some leakage occurs, the wire segments are still "occlusion-forming" since the occlusion is still formed even though it is not perfect. In any event, assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an

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anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed position. Alternatively, the Munster wire segments are obviously "occlusion-forming" for the reasons set forth above. As to claims 4, 18, 24, 35 and 41, Munster shows foldable membranes (opposite end portions of the balloon described on page 10, lines 23-25). It is clear that the Munster balloon is long enough such that it extends as far as the wire segments on opposite sides of the aperture (at end portions 2 and 3 of the occluding device 1) so that the end portions of the balloon are "associated with" the wire segments on opposite sides of the aperture, as claimed. This is because the central portion of the balloon possesses a narrowed waist which is located around the central bridge or narrowed waist 5 of the occluding device 1, leaving the end portions of the balloon (on opposites ends of the narrowed waist) located at end portions 2 and 3 of the occluding device 1. As to claims 37 and 43, the Munster domed member formed by the membrane and wire segments is outwardly convex since the outer edge or periphery of the domed member is outwardly convex.

Claims 6-8, 10, 12, 13, 16, 17, 20, 22, 26, 31, 33, 40 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303). As to claims 6, 16, 20, 26, 31, 40 and 45, Munster fails to show nitinol as the temperature responsive

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material. However, nitinol is well known in the art as being a material which is very responsive to temperature change. It would have been obvious to use nitinol as the Munster temperature responsive material for this reason. As to claims 10, 20, 26 and 31, Munster fails to show spring steel as the shape memory retentive material. However, spring steel is well known in the art as being a material which returns to its shape effectively. It would have been obvious to use as spring steel the Munster shape memory retentive material for this reason. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious since it is well known in this art to include such a coating on implantable members for this reason. As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since it is well known in this art that such defects may be corrected by an occluding device.

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303) in view of Kamiya et al. (5,192,301). As to claims 1, 9 and 28, assuming arguendo that the Munster wire segments themselves are not "occlusion-forming", Kamiya et al. teach that the flange portions of a temperature responsive plug which are on opposite sides of the aperture which is to be occluded should be themselves "occlusion-forming" in order

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to form an effective seal (col. 3, lines 56-60 and figures 10a and 10b for example). It would have been obvious to make the Munster wire segments on opposite sides of the aperture "occlusion-forming" in order to reduce or eliminate any leakage of blood in view of this teaching. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious in view of the Kamiya et al. teaching of so coating the occluding member apparently for this reason (col. 7, lines 22-28). As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since Kamiya et al. teach that such defects may be corrected by an occluding device (col. 1, lines 15-18).

The declaration filed on June 20, 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Kamiya et al. reference. The declaration fails to contain an allegation that the acts relied upon to establish the date prior to the reference were carried out in this country or in a NAFTA country or WTO member country as required by 35 U.S.C. 104. Note M.P.E.P. 715.07 (c). The declaration is otherwise acceptable.

Patent Owner's arguments as well as the declaration of Lloyd A. Marks under 37 C.F.R. 1.132 filed June 20, 2002 have been fully considered but they are not persuasive. The argument on pages 10-12 of the response that the original disclosure of the Marks patent

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in catheter 4 as seen in figure 3, for example and described on page 8, paragraph f and page 12, lines 3-9) and a preprogrammed configuration which includes occlusion-forming wire segments, one on each side of the aperture, urged toward one another. The wire segments have been "urged toward one another" since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. The wire segments are inherently "occlusion-forming" since they are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Although the formation of the occlusion may be supplemented by the swelling plastic or the balloon described on page 9, paragraph j, the wire segments themselves are inherently "occlusion-forming" since they come to rest against the tissue on both sides of the aperture and therefore form a blockage for the blood. Even if this blockage is not perfect, i.e. even if some leakage occurs, the wire segments are still "occlusion-forming" since the occlusion is still formed even though it is not perfect. In any event, assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an

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anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed position. Alternatively, the Munster wire segments are obviously "occlusion-forming" for the reasons set forth above. As to claims 4, 18, 24, 35 and 41, Munster shows foldable membranes (opposite end portions of the balloon described on page 10, lines 23-25). It is clear that the Munster balloon is long enough such that it extends as far as the wire segments on opposite sides of the aperture (at end portions 2 and 3 of the occluding device 1) so that the end portions of the balloon are "associated with" the wire segments on opposite sides of the aperture, as claimed. This is because the central portion of the balloon possesses a narrowed waist which is located around the central bridge or narrowed waist 5 of the occluding device 1, leaving the end portions of the balloon (on opposites ends of the narrowed waist) located at end portions 2 and 3 of the occluding device 1. As to claims 37 and 43, the Munster domed member formed by the membrane and wire segments is outwardly convex since the outer edge or periphery of the domed member is outwardly convex.

Claims 6-8, 10, 12, 13, 16, 17, 20, 22, 26, 31, 33, 40 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303). As to claims 6, 16, 20, 26, 31, 40 and 45, Munster fails to show nitinol as the temperature responsive

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material. However, nitinol is well known in the art as being a material which is very responsive to temperature change. It would have been obvious to use nitinol as the Munster temperature responsive material for this reason. As to claims 10, 20, 26 and 31, Munster fails to show spring steel as the shape memory retentive material. However, spring steel is well known in the art as being a material which returns to its shape effectively. It would have been obvious to use as spring steel the Munster shape memory retentive material for this reason. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious since it is well known in this art to include such a coating on implantable members for this reason. As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since it is well known in this art that such defects may be corrected by an occluding device.

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303) in view of Kamiya et al. (5,192,301). As to claims 1, 9 and 28, assuming arguendo that the Munster wire segments themselves are not "occlusion-forming", Kamiya et al. teach that the flange portions of a temperature responsive plug which are on opposite sides of the aperture which is to be occluded should be themselves "occlusion-forming" in order

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to form an effective seal (col. 3, lines 56-60 and figures 10a and 10b for example). It would have been obvious to make the Munster wire segments on opposite sides of the aperture "occlusion-forming" in order to reduce or eliminate any leakage of blood in view of this teaching. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious in view of the Kamiya et al. teaching of so coating the occluding member apparently for this reason (col. 7, lines 22-28). As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since Kamiya et al. teach that such defects may be corrected by an occluding device (col. 1, lines 15-18).

The declaration filed on June 20, 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Kamiya et al. reference. The declaration fails to contain an allegation that the acts relied upon to establish the date prior to the reference were carried out in this country or in a NAFTA country or WTO member country as required by 35 U.S.C. 104. Note M.P.E.P. 715.07 (c). The declaration is otherwise acceptable.

Patent Owner's arguments as well as the declaration of Lloyd A. Marks under 37 C.F.R. 1.132 filed June 20, 2002 have been fully considered but they are not persuasive. The argument on pages 10-12 of the response that the original disclosure of the Marks patent

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indicates that the wire ribs 23a-c, 23'a-c in the embodiments of figures 1-5 are "helical coils" is not well taken. First, claim 9 requires the wire (singular) to include occlusion-forming wire segments one (singular) on each side of the aperture, wherein the occlusion-forming segments each (singular) comprise "helical coils". Claim 28 has a similar limitation wherein the occlusion-forming wire segments each comprise helical coils. Each of the wire ribs 23a-c, 23'a-c does not form "coils" since each wire rib extends circumferentially less than 360 degrees thus does not even form one coil. For example, if the claimed "wire" is considered to be wire 23a, 23'a, then occlusion-forming wire segment 23a extends circumferentially less than 360 degrees and thus does not even form one coil, much less a plurality of coils. Second, a helix (even as defined by the definition supplied by Patent Owner) requires the curve to lie on a cylinder or cone and cut the elements at a constant angle. Assuming that the variations in septal thickness (described in paragraphs 9 and 10 in the declaration of Lloyd A. Marks under 37 C.F.R. 1.132) result in the circumferential portions of the wire not lying flat but rather varying with the variations in septal thickness (paragraph 10 of the declaration), then there is no evidence that the angle of the wire ribs would necessarily be at a constant angle as required. In other words, there is no evidence that a single wire rib would necessarily lie at a constant angle from one end of the circumferential portion of the rib to the

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other. Also, there is no evidence that each of the wire ribs would necessarily lie at the same angle of the other ribs. Third, all indications from the specification and drawings are that the circumferential portions of the wire ribs lie in the same plane both while they are within the catheter and while they are outside of the catheter as seen in figure 1, for example.

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The arguments on pages 12-18 of the response regarding Munster are not well taken. Patent Owner alleges on page 14 that the wire ends 2, 3 of Munster are not occluding elements since occlusion is accomplished only by the swelling of the central bridge 5 by plastic foam on a balloon or by textile fibers or bristles. This allegation is simply incorrect. Textile fibers or bristles extend all along the wire ends 2, 3 as seen in figure 1 of Munster. Thus, the wire ends 2, 3, which support the bristles, act as occluding elements. Note that the wire ribs 23a-c, 23'a-c of the Marks patent are considered to be occluding elements even though they merely support the membranes 21a, 21b which form the occlusion in the embodiments of figures 1-5. Patent Owner argued in the interview held April 11, 2002 and reiterates on pages 16-18 of the response that the phrase "preprogrammed configuration which includes occlusion-forming wire segments one on each side urged toward one another" in the claims requires the wire segments to be pressing against one another without any tissue therebetween. Specifically, Patent Owner argues on page 16 that the

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"preprogrammed configuration" of the wire in Marks patent is the condition of the occluding device when it is manufactured (and not within the human body). It was argued that in this condition, as manufactured, the wire segments press against one another with no tissue therebetween and are thus "urged toward one another". It was then argued that the wire segments of Munster are separated when they are in the "preprogrammed configuration" and thus are not pressing directly against one another and thus are not "urged toward one another". There are several problems with this interpretation. First, as to the question of what the "preprogrammed configuration" is, the Marks patent makes it crystal clear what the "preprogrammed configuration" is. Both the specification and claims indicate that the "preprogrammed configuration" of the wire is the configuration of the wire while it is within the body (and not when it is manufactured but prior to placement within the body). For example, claim 1 defines the "preprogrammed configuration" of the wire to be the configuration in which the wire segments are located on each side of the aperture (and thus within the body). Also, similar language appears in col. 3, lines 3-8 of the specification. There is no indication from the Marks disclosure that the wire segments actually touch one another when no tissue is therebetween. The disclosure is silent on this point. In any event, the Munster wire segments are clearly urged toward one another since they move radially outward and

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longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. Thus, there is a biasing force which urges the Munster wire segments toward one another. Further, the wire segments are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Thus, even if the Munster wire segments, when they come to rest against the tissue, do not press against the tissue even in the slightest amount as they touch it (which is extremely unlikely as set forth below), they still have been "urged toward each other" as they moved toward each other. The claims do not require the wire segments to be (in the present) actively pressing against the tissue and urging toward one another. However, assuming *arguendo* that the claims require this, it certainly would be very difficult, if not impossible, to size the Munster occluding member so that the wire segments, when they come to rest against the tissue, would not press against the tissue even an infinitesimal amount (i.e. with exactly zero force). Note that the amount "urged" is not claimed. However, even if this unlikely event happened, the Munster wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would inherently press against the tissue since they would be away from their at rest, relaxed position and

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thus be "urged toward each other" even in this specific interpretation of the phrase. Also, there is no teaching in Munster that the wire segments, as they are intended to operate, do not press against the tissue. It certainly would have been obvious to size them so that they press against tissue when implanted in the body in order to insure that they come to rest against tissue as intended.

As to the argument in the paragraph bridging pages 15 and 16, first, a comparison of figures 1 and 3 of Munster is not particularly relevant since these figures denote different embodiments. Second, a comparison of figures 3 and 4 (which show the same occluding member inside the catheter in figure 3 and outside the catheter in figure 4) show that arms 8 move longitudinally toward each other as the occluding member is deployed and thus are urged toward each other during this movement.

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, which will be strictly enforced.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

mht  
August 12, 2002  
FAX (703) 305-3590

  
MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731

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**EXHIBIT N - Part 2**


**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	JUNE 25, 2001	5,108,420	000365-00002

BLANK ROME COMISKY & MCCAULEY, LLP  
900 17<sup>TH</sup> STREET, N. W., SUITE 1000  
WASHINGTON, DC 20006

EXAMINER

THALER, M.

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23

DATE MAILED: FEBRUARY 5, 2003 *AK*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED:

## OFFICE ACTION IN REEXAMINATION

☒ Responsive to the communication(s) filed on DEC. 2, 2002 ☒ This action is made FINAL.

A shortened statutory period for response to this action is set to expire ONE month(s) from the date of this letter. Failure to respond within the period for response will cause termination of the proceeding and issuance of a reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(e).**

### PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 3. ☐ Notice of Informal Patent Drawing, PTO-948.  
2. ☐ Information Disclosure Citation, PTO-1449. 4. ☐ \_\_\_\_\_

### PART II SUMMARY OF ACTION:

1. ☒ Claims 1-80 are subject to reexamination.  
2. ☐ Claims \_\_\_\_\_ are not subject to reexamination.  
3. ☐ Claims \_\_\_\_\_ have been cancelled.  
4. ☐ Claims \_\_\_\_\_ are confirmed.  
5. ☐ Claims \_\_\_\_\_ are patentable.  
6. ☒ Claims 1-80 are rejected.  
7. ☐ Claims \_\_\_\_\_ are objected to.  
8. ☐ The formal drawings filed on \_\_\_\_\_ are acceptable.  
9. ☒ The drawing correction request filed on DEC. 2, 2002 is ☒ approved, ☐ disapproved.  
10. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received, ☐ not been received, ☐ been filed in Serial No. \_\_\_\_\_ filed on \_\_\_\_\_.  
11. ☐ Since the proceeding appears to be in condition for issuance of a reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 435 O.G. 213.  
12. ☐ Other

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The amendment filed Dec. 2, 2002 does not comply with 37 CFR 1.530(d)(1), (d)(2) and (f) since the clean version does not show changes made to the specification relative to the patent with appropriate markings (bracketing and underlining). Further, claims 28, 31 and 32 are not completely underlined as they should be since they are new relative to the patent. Any future response should correct these matters.

The drawing correction request filed on Dec. 2, 2002 is approved.

Claims 18 and 22-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 is limited to the embodiment of figures 6-9 since the embodiment of figures 1-5 fails to include helical coils as defined in claim 9, line 12. The original disclosure fails to disclose a membrane in the embodiment of figures 6-9. In fact, it is unclear how one could even include a membrane in this embodiment due to the manner in which helixes 62a and 62b are deployed as explained in col.5, lines 38-68. Thus, there is no basis in the original disclosure for the membrane defined in claims 18, 22, 24, 29 and 33, each of which depends from a claim (claim 9) which is limited to the embodiment of figures 6-9. Further, claims 23 and 25, which

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also depend from claim 9, each define more than one wire. The only embodiments which include more than one wire are the embodiments of figures 1-5. The original disclosure fails to disclose a plurality of wires in the embodiment of figures 6-9. Thus, there is no basis in the original disclosure for the plurality of wires defined in claims 23 and 25, each of which depends from a claim (claim 9) which is limited to the embodiment of figures 6-9. Claim 28 is similarly defective since it includes both a plurality of wires and helical coils.

Claims 1-5, 9, 11, 14, 15, 18, 19, 21, 23-25, 27-31, 33-39, 41-44, 46-64, 66-68, 70-75, 77, 78 and 80 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Munster (Germany 233,303). Munster shows a device 1 (either the embodiment of figure 1 or the embodiment of figure 2) to occlude an aperture within a body surface comprising a wire having an elongated configuration (the stretched form of the wire while it is in catheter 4 as seen in figure 3, for example and described on page 8, paragraph f and page 12, lines 3-9) and a preprogrammed configuration which includes occlusion-forming wire segments, one on each side of the aperture, urged toward one another. The wire segments have been "urged toward one another" since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12,

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lines 10-20. The wire segments are inherently "occlusion-forming" since they are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Although the formation of the occlusion may be supplemented by the swelling plastic or the balloon described on page 9, paragraph j, the wire segments themselves are inherently "occlusion-forming" since they come to rest against the tissue on both sides of the aperture and therefore form a blockage for the blood. Even if this blockage is not perfect, i.e. even if some leakage occurs, the wire segments are still "occlusion-forming" since the occlusion is still formed even though it is not perfect. In any event, assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed position. Alternatively, the Munster wire segments are obviously "occlusion-forming" for the reasons set forth above. As to claims 4, 18, 24, 33, 35, 41, 55, 67, 67, 75 and 78, Munster discloses foldable membranes (opposite end portions of the balloon described on page 10, lines 23-25). It is

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clear that the Munster balloon is long enough such that it extends as far as the wire segments on opposite sides of the aperture (at end portions 2 and 3 of the occluding device 1) so that the end portions of the balloon are "associated with" the wire segments on opposite sides of the aperture, as claimed. This is because the central portion of the balloon possesses a narrowed waist which is located around the central bridge or narrowed waist 5 of the occluding device 1, leaving the end portions of the balloon (on opposites ends of the narrowed waist) located at end portions 2 and 3 of the occluding device 1. As to claims 37 and 43 and 54, the Munster domed member formed by the membrane and wire segments is outwardly convex since the outer edge or periphery of the domed member is outwardly convex. In other words, the outer edge or periphery is outwardly convex in the same manner that the outer edge or periphery of a disc is outwardly convex. As to claim 48, the Munster wire segment in figure 1 is configured to form a circular periphery (at the extreme left and right ends of the device) with a center, the wire segment extending from the center (at central bridge 5) to the periphery (in a helical fashion). Although the central bridge 5 is not precisely at the geometric center point of the circular periphery, the term "center" is considered to be the general central area of the circular periphery. The central bridge 5 is located at the center in this sense. Note that wire ribs 23a-d and 23'a-d of the Marks patent do

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not extend completely to the geometric center point of the circular periphery as seen in amended figures 1 and 5, for example. Rather, the axial rod which supports eye 25 is at the exact center while the wire ribs 23a-d and 23'a-d are radially spaced from the exact center and are located around the axial rod. As to claims 50 and 51, the wire segments shown in figure 2 of Munster extend generally radially and along a radius as claimed. As to claims 52 and 53, each of the Munster wire segments in figure 1 extends from the center (helically) and also curves and extends circumferentially to the periphery at the outermost winding of the helix. As to claim 60, the figure 1 Munster wire segments at the outermost periphery are inherently configured to engage and press against a body which is thick enough near the outermost periphery such that the body surface engages the wire segments at the outermost periphery.

Claims 6-8, 10, 12, 13, 16, 17, 20, 22, 26, 32, 40, 45 and 65, 69, 76 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303). As to claims 6, 16, 20, 26, 32, 40 and 45, Munster fails to show nitinol as the temperature responsive material. However, nitinol is well known in the art as being a material which is very responsive to temperature change. It would have been obvious to use nitinol as the Munster temperature responsive material for this reason. As to claims 10, 20, 26 and 32, Munster fails to show spring steel as the shape memory retentive material. However, spring steel is well known in

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the art as being a material which returns to its shape effectively. It would have been obvious to use as spring steel the Munster shape memory retentive material for this reason. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious since it is well known in this art to include such a coating on implantable members for this reason. As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since it is well known in this art that such defects may be corrected by an occluding device. As to claims 65, 69, 76 and 79, Munster fails to show stitching. However, using stitching to secure the membrane (the balloon described on page 10, lines 23-25) to the wire in order to insure that it does not become detached would have been obvious since stitching in general is a well known securing means in this art.

The declarations filed on June 20, 2002 and Dec. 2, 2002 under 37 CFR 1.131 are sufficient to overcome the Kamiya et al. (5,192,301) reference.

Patent Owner's arguments filed Dec. 2, 2002 have been fully considered but they are not persuasive. The argument on pages 9-11 of the response that the original disclosure of the Marks patent indicates that the wire ribs 23a-c, 23'a-c in the embodiments of figures 1-5 are "helical coils" is not well taken. First, claim 9

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requires the wire (singular) to include occlusion-forming wire segments one (singular) on each side of the aperture, wherein the occlusion-forming segments each (singular) comprise "helical coils". Claim 28 has a similar limitation wherein the occlusion-forming wire segments each comprise helical coils. Each of the wire ribs 23a-c, 23'a-c does not form "coils" since each wire rib extends circumferentially less than 360 degrees and thus does not even form one coil. For example, if the claimed "wire" is considered to be wire 23a, 23'a, then occlusion-forming wire segment 23a extends circumferentially less than 360 degrees and thus does not even form one coil, much less a plurality of coils. Second, a helix (even as defined by the definition supplied by Patent Owner) requires the curve to lie on a cylinder or cone and cut the elements at a constant angle. Assuming that the variations in septal thickness (described in paragraphs 9 and 10 in the declaration of Lloyd A. Marks under 37 C.F.R. 1.132) result in the circumferential portions of the wire not lying flat but rather varying with the variations in septal thickness (paragraph 10 of the declaration), then there is no evidence that the angle of the wire ribs would necessarily be at a constant angle as required. In other words, there is no evidence that a single wire rib would necessarily lie at a constant angle from one end of the circumferential portion of the rib to the other. Also, there is no evidence that each of the wire ribs would necessarily lie at the

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same angle of the other ribs. Third, all indications from the specification and drawings are that the circumferential portions of the wire ribs lie in the same plane both while they are within the catheter and while they are outside of the catheter as seen in figure 1, for example. In figure 1, the left portion of the occlusion device is within the catheter. The extreme left end of this left portion of the occlusion device is shown as a vertical line which indicates that the circumferential portions of the wires lie in the same plane (defined by the vertical line). Even if the circumferential portions of the wires overlap one another in the circumferential direction, this does not indicate that they are helical. Each circumferential portion could bend slightly where it meets the radial portion while still remaining planar. Further, there is no indication from the Marks patent that the circumferential, arc-shaped segment of wire portion 23'a, for example, when compressed within the catheter, extends at least 720 degrees to form a plurality of coils. In any event, claim 9 requires the wire to include helical coils when it is in the "preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture" also noting "wherein said occlusion forming segments each comprise helical coils urged toward one another" (underlining added). Thus, even assuming arguendo that the wire in the figure 1-4 embodiment of Marks is helical when it is within the catheter (which it is not), it is not

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helical when it is in the preprogrammed configuration (which includes occlusion-forming wire segments one on each side of said aperture) which is the configuration claimed to be helical. Fourth, in col. 2, lines 3-7 of the Marks patent, it is stated, "In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes..."

(underlining added). This indicates that one embodiment includes helices while the other does not. Also, in col. 3, lines 37-40, it is stated, "In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.". This indicates that only one embodiment (not both embodiments) forms coiled helices.

The arguments on pages 12-18 of the June 20, 2002 response and pages 11-19 of the Dec. 2, 2002 response regarding Munster are not well taken. Patent Owner alleges on page 14 of the June 20, 2002 response and page 15-17 of the Dec. 2, 2002 response that the wire ends 2, 3 of Munster are not occluding elements since occlusion is accomplished only by the swelling of the central bridge 5 by plastic foam on a balloon or by textile fibers or bristles. This allegation is simply incorrect. Textile fibers or bristles 9 extend all along the wire ends 2, 3 as seen in figure 1 of Munster. Thus, the wire ends 2, 3, which support the bristles, act as

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occluding elements. Note that the wire ribs 23a-c, 23'a-c of the Marks patent are considered to be occluding elements even though they merely support the membranes 21a, 21b which form the occlusion in the embodiments of figures 1-5. Patent Owner argued in the interview held April 11, 2002 and reiterates on pages 16-18 of the June 20, 2002 response that the phrase "preprogrammed configuration which includes occlusion-forming wire segments one on each side urged toward one another" in the claims requires the wire segments to be pressing against one another without any tissue therebetween. Specifically, Patent Owner argues on page 16 that the "preprogrammed configuration" of the wire in Marks patent is the condition of the occluding device when it is manufactured (and not within the human body). It was argued that in this condition, as manufactured, the wire segments press against one another with no tissue therebetween and are thus "urged toward one another". It was then argued that the wire segments of Munster are separated when they are in the "preprogrammed configuration" and thus are not pressing directly against one another and thus are not "urged toward one another". There are several problems with this interpretation. First, as to the question of what the "preprogrammed configuration" is, the Marks patent makes it crystal clear what the "preprogrammed configuration" is. Both the specification and claims indicate that the "preprogrammed configuration" of the wire is the configuration of the wire while

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it is within the body (and not when it is manufactured but prior to placement within the body). For example, claim 1 defines the "preprogrammed configuration" of the wire to be the configuration in which the wire segments are located on each side of the aperture (and thus within the body). Also, similar language appears in col. 3, lines 3-8 of the specification. There is no indication from the Marks disclosure that the wire segments actually touch one another when no tissue is therebetween. The disclosure is silent on this point. In any event, the Munster wire segments are clearly urged toward one another since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. Thus, there is a biasing force which urges the Munster wire segments toward one another. Further, the wire segments are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Thus, even if the Munster wire segments, when they come to rest against the tissue, do not press against the tissue even in the slightest amount as they touch it (which is extremely unlikely as set forth below), they still have been "urged toward each other" as they moved toward each other. Claims 1-61 and 72-80 do not require the wire segments to be (in the present) actively pressing against the tissue and urging toward one another.

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However, assuming *arguendo* that the claims require this, it certainly would be very difficult, if not impossible, to size the Munster occluding member so that the wire segments, when they come to rest against the tissue, would not press against the tissue even an infinitesimal amount (i.e. with exactly zero force). Note that the amount "urged" is not claimed. However, even if this unlikely event happened, the Munster wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would inherently press against the tissue since they would be away from their at rest, relaxed position and thus be "urged toward each other" even in this specific interpretation of the phrase. Also, there is no teaching in Munster that the wire segments, as they are intended to operate, do not press against the tissue. It certainly would have been obvious to size them so that they press against tissue when implanted in the body in order to insure that they come to rest against tissue as intended.

As to the argument in the paragraph bridging pages 15 and 16 of the June 20, 2002 response, first, a comparison of figures 1 and 3 of Munster is not particularly relevant since these figures denote different embodiments. Second, a comparison of figures 3 and 4 (which show the same occluding member inside the catheter in figure 3 and outside the catheter in figure 4) show that arms 8 move longitudinally toward each other as the occluding member is

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deployed and thus are urged toward each other during this movement.

As to the argument on page 19 of the Dec. 2, 2002 response regarding claim 2, Munster discloses the claimed means for holding the wire, which includes holding wire 7.

**THIS ACTION IS MADE FINAL.**

A shortened statutory period for response to this action is set to expire one month from the mailing date of this action.

Extensions of time under 37 CFR 1.136(a) do not apply in reexamination proceedings. The provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Further, in 35 U.S.C. 305 and in 37 CFR 1.550(a), it is required that reexamination proceedings "will be conducted with special dispatch within the Office."

Extensions of time in reexamination proceedings are provided for in 37 CFR 1.550(c). A request for extension of time must be filed on or before the day on which a response to this action is due. The mere filing of a request will not effect any extension of time. An extension of time will be granted only for sufficient cause, and for a reasonable time specified.

The filing of a timely first response to this final rejection will be construed as including a request to extend the shortened statutory period for an additional month, which will be granted even if previous extensions have been granted. In no event however, will the statutory period for response expire later than

Application/Control Number: 90/006,043

Page 15

Art Unit: 3731

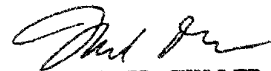
SIX MONTHS from the mailing date of the final action. See MPEP § 2265.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
January 28, 2003

  
MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731

  
David Reip  
Primary Examiner  
(conferee)

  
Kevin Truong  
Primary Examiner  
(conferee)


**Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	JUNE 25, 2001	5,108,420	000365-00002

BLANK ROME COMISKY & MCCAULEY, LLP  
 900 17<sup>TH</sup> STREET, N.W.  
 SUITE 1000  
 WASHINGTON, DC 20006

**EXAMINER**

THALER, M.

ART UNIT	PAPER
3731	27

 DATE MAILED: APRIL 25, 2003 *AL*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark OfficeAddress: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
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90/006,043

EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

# 28  
29 AC

## REEXAMINATION ADVISORY ACTION

1. ☒ THE PERIOD FOR RESPONSE IS EXTENDED TO RUN FOUR MONTH(S) FROM THE DATE OF THE FINAL REJECTION. CAUTION: Fee extensions of time are not available in reexamination proceedings. Extensions of time for sufficient cause may be available under 37 CFR 1.550(c).
2. ☐ Appellant's Appeal Brief is due in accordance with 37 C.F.R. 1.192(a).
3. ☒ Patent owner's response to the final rejection, filed on 4-4-03, has been considered with the following effect, but it is not deemed to place the reexamination in condition for issuance of a reexamination certificate.
4. ☒ The proposed amendments to the claim(s) and/or specification will not be entered and the final rejection stands because:
  - a. ☐ There is no convincing showing under 37 C.F.R. 1.116(b).
  - b. ☒ They raise new issues that would require further consideration and/or search.
  - c. ☐ They raise the issue of new matter.
  - d. ☐ They are not deemed to place the reexam in better form for appeal by materially reducing or simplifying the issues for appeal.
  - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be patentable if submitted in a separately filed amendment cancelling the rejected claims.
6. ☒ Upon the filing of an appeal, the proposed amendment ☐ will be, ☒ will not be, entered and the status of the claims in this reexamination would be as follows:
  - a. ☐ Claim(s) \_\_\_\_\_ would be confirmed.
  - b. ☐ Claim(s) \_\_\_\_\_ would be patentable.
  - c. ☒ Claim(s) 1-80 would not be patentable.
    - (1) ☐ The rejection claim(s) \_\_\_\_\_ on references is deemed to be overcome by owner's response.
    - (2) ☐ The rejection of claim(s) \_\_\_\_\_ on non-reference grounds only is deemed to be overcome by owner's response.
7. ☐ The affidavit, declaration, exhibit or request for reconsideration has been entered but does not overcome the rejection.
8. ☐ The affidavit, declaration, or exhibit will not be admitted because owner has not shown good and sufficient reasons why it was not earlier presented.
9. ☐ The proposed drawing correction ☐ is, ☐ is not, approved.
10. ☒ Other: PLEASE SEE THE ATTACHED PAGE.

cc: Requester  
PTOL-467 (2/93)

Application/Control Number: 90/006,043

Page 2

Art Unit: 3731

The new issues arise from the new terms in claims 37 and 54.

It is clear from the Munster specification and drawings that the wire segments (wires segments 8 in figure 2 for example, on only the right side of the figure) move radially outwardly apart from each other and longitudinally toward the wire segments 8 on the opposite (left) side of the figure.

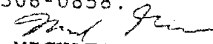
As to claims 38, 39, 44 and 46, the shape shown in figure 1 of Munster meets the claim language because of the term "substantially" in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
April 23, 2003

  
MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	JUNE 25, 2001	5,108,420	000365-00002

BLANK ROME COMISKY & MCCAULEY, LLP  
900 17<sup>TH</sup> STREET, N.W.  
SUITE 1000  
WASHINGTON, DC 20006

EXAMINER

THALER, M.

ART UNIT	PAPER
3731	29

DATE MAILED: MAY 29, 2003

*JK*

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Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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29

DATE MAILED:

### REEXAMINATION ADVISORY ACTION

1. ☒ THE PERIOD FOR RESPONSE IS EXTENDED TO RUN FOUR MONTH(S) FROM THE DATE OF THE FINAL REJECTION. CAUTION: Fee extensions of time are not available in reexamination proceedings. Extensions of time for sufficient cause may be available under 37 CFR 1.550(c).
2. ☐ Appellant's Appeal Brief is due in accordance with 37 C.F.R. 1.192(a).
3. ☒ Patent owner's response to the final rejection, filed on 5-7-03, has been considered with the following effect, but it is not deemed to place the reexamination in condition for issuance of a reexamination certificate.
4. ☐ The proposed amendments to the claim(s) and/or specification will not be entered and the final rejection stands because:
  - a. ☐ There is no convincing showing under 37 C.F.R. 1.116(b).
  - b. ☐ They raise new issues that would require further consideration and/or search.
  - c. ☐ They raise the issue of new matter.
  - d. ☐ They are not deemed to place the reexam in better form for appeal by materially reducing or simplifying the issues for appeal.
  - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be patentable if submitted in a separately filed amendment cancelling the rejected claims.
6. ☒ Upon the filing of an appeal, the proposed amendment ☒ will be, ☐ will not be, entered and the status of the claims in this reexamination would be as follows:
  - a. ☐ Claim(s) \_\_\_\_\_ would be confirmed.
  - b. ☐ Claim(s) \_\_\_\_\_ would be patentable.
  - c. ☒ Claim(s) 1-17, 19-21, 34-80 would not be patentable.
    - (1) ☐ The rejection claim(s) \_\_\_\_\_ on references is deemed to be overcome by owner's response.
    - (2) ☐ The rejection of claim(s) \_\_\_\_\_ on non-reference grounds only is deemed to be overcome by owner's response.
7. ☒ The affidavit, declaration, exhibit or request for reconsideration has been entered but does not overcome the rejection.
8. ☐ The affidavit, declaration, or exhibit will not be admitted because owner has not shown good and sufficient reasons why it was not earlier presented.
9. ☐ The proposed drawing correction ☐ is, ☐ is not, approved.
10. ☐ Other:

cc: Requester  
PTOL-467 (2/93)

MICHAEL H. THALER  
PRIMARY EXAMINER  
GROUP 3200

**EXHIBIT O**

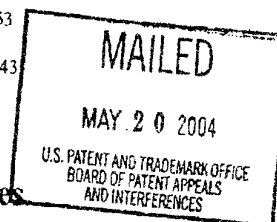


**UNITED STATES PATENT AND TRADEMARK OFFICE**

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

BLANK ROME LLP  
600 NEW HAMPSHIRE AVENUE, N.W.  
WASHINGTON, DC 20037

Paper No: 35  
Appeal No: 2004-1453  
Appellant: 5108420  
Application: 90/006,043



**Board of Patent Appeals and Interferences  
Docketing Notice**

Application 90/006,043 was received from the Technology Center at the Board on March 29, 2004 and has been assigned Appeal No: 2004-1453.

A review of the file indicates that the following documents have been filed by appellant:

Appeal Brief filed on: June 17, 2003  
Reply Brief filed on: October 12, 2003  
Request for Hearing filed on: November 23, 2003

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

**BOARD OF PATENT APPEALS AND INTERFERENCES  
UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. BOX 1450  
ALEXANDRIA, VIRGINIA 22313-1450**

The facsimile number of the Board is 703-308-7952. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 703-308-9797 and should be directed to a Program and Resource Administrator.

By order of the Board of Patent Appeals and Interferences



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U.S. PATENT AND TRADEMARK OFFICE  
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AND INTERFERENCESBlank Rome LLP  
600 New Hampshire Avenue, N.W.  
Washington, DC 20037Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, Virginia  
22313-11450  
www.uspto.gov

Paper No: 36

Appeal No:	2004-1453
Appellant:	5108420, Lloyd Marks
Application No:	90/006,043
Hearing Room:	B
Hearing Docket:	B
Hearing Date:	Thursday, July 15, 2004
Hearing Time:	9:00 AM
Location:	Room 12C07 CRYSTAL GATEWAY 2 1225 Jefferson Davis Highway Arlington, VA 22202

## NOTICE OF HEARING

## CONFIRMATION REQUIRED WITHIN TWENTY-ONE DAYS

Your attention is directed to 37 CFR § 1.194(a).

The above identified appeal will be heard by the Board of Patent Appeals and Interferences on the date indicated. Hearings will commence at the time set and as soon as the argument in one appeal is concluded, the succeeding appeal will be taken up.

The time allowed for argument is twenty minutes unless additional time is requested and permitted before the argument is commenced.

## CONFIRMATION OR WAIVER OF THE HEARING IS REQUIRED.

This form must be completed below and facsimile transmitted to both: (1) the USPTO Central fax number (official copy), and (2) the Board of Patent Appeals and Interferences fax number (courtesy copy) within TWENTY-ONE (21) DAYS from the mailing date of this notice indicating confirmation or waiver of the hearing. A copy of this notice may be alternately filed by mail if facsimile is not available.

Failure to file this form within this time period will be construed as a waiver of the request for oral hearing.

37 CFR § 1.136(a) does not apply.

By order of the Board of Patent Appeals and Interferences

BPAI HEARINGS FAX No:

(703) 308-6199

USPTO Central Fax No.

(703) 872-9306

BPAI Mailing Address:

BOARD OF PATENT APPEALS AND INTERFERENCES

UNITED PATENT AND TRADEMARK OFFICE

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ALEXANDRIA, VIRGINIA 22313-11450

Clerk of the Board (703)-308-9797

In all communications relating to this appeal, please identify the appeal by its number.

CHECK ONE:

☐ HEARING ATTENDANCE CONFIRMED☐ HEARING ATTENDANCE WAIVED

Signature of Attorney/Agent/Appellant

Date

Registration No.

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GEORGE MYERS

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U.S. PATENT AND TRADEMARK OFFICE  
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P.O. Box 1450  
Alexandria, Virginia  
22313-11450  
www.uspto.gov

Paper No: 32

Appeal No:

2004-1453

Appellant:

5108420, Lloyd Marks

Application No:

90/008,043

Hearing Room:

3

Hearing Docket:

8

Hearing Date:

Thursday, July 16, 2004

Hearing Time:

9:00 AM

Location:

Room 12C07  
CRYSTAL GATEWAY 2  
1225 Jefferson Davis Highway  
Arlington, VA 22202

Blank Rome LLP

600 New Hampshire Avenue, N.W.  
Washington, DC 20037

## NOTICE OF HEARING

## CONFIRMATION REQUIRED WITHIN TWENTY-ONE DAYS

Your attention is directed to 37 CFR § 1.194(a).

The above identified appeal will be heard by the Board of Patent Appeals and Interferences on the date indicated. Hearings will commence at the time set and as soon as the argument in one appeal is concluded, the succeeding appeal will be taken up.

The time allowed for argument is twenty minutes unless additional time is requested and permitted before the argument is commenced.

## CONFIRMATION OR WAIVER OF THE HEARING IS REQUIRED.

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Failure to file this form within this time period will be construed as a waiver of the request for oral hearing.

37 CFR § 1.128(a) does not apply.

By order of the Board of Patent Appeals and Interferences

BPAI HEARINGS FAX No:

(703) 308-6189

USPTO Central Fax No.

(703) 872-9306

BPAI Mailing Address:

BOARD OF PATENT APPEALS AND INTERFERENCES

UNITED PATENT AND TRADEMARK OFFICE

P.O. BOX 1450

ALEXANDRIA, VIRGINIA 22313-11450

Clerk of the Board (703)-308-9797

In all communications relating to this appeal, please identify the appeal by its number.

CHECK ONE:

- ☒ HEARING ATTENDANCE CONFIRMED  
☐ HEARING ATTENDANCE WAIVED

Signature of Attorney/Agent/Appellant

Date

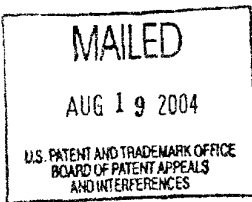
Registration No.

*Staab/Prog.*

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE



BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte LLOYD MARKS

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

HEARD: July 15, 2004

Before COHEN, STAAB, and NASE, Administrative Patent Judges.  
STAAB, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1-80 in this patentee requested reexamination proceeding for U.S. Patent No. 5,106,420. Two proposed amendments have been submitted subsequent to the final rejection. The first amendment after final (Paper No. 26) was refused entry. The second amendment after final (Paper No. 28) was entered, and as a consequence claims 18 and 22-33 were canceled. In addition, upon

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

further review the examiner has withdrawn the rejection as to dependent claims 65, 69, 76 and 79, and indicated that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Accordingly, the appeal as to claims 65, 69, 76 and 79 is dismissed, leaving for our consideration only the standing rejections of claims 1-17, 19-21, 34-64, 66-68, 70-75, 77, 78 and 80. Of these remaining claims, claims 1-14 correspond to claims 1-14 of the patent, and claims 15-17, 19-21, 34-64, 66-68, 70-75, 77, 78 and 80 are new claims added during prosecution.

#### The Invention

Appellant's invention relates to devices and methods used to occlude (i.e., block blood flow through) an aperture within a body surface of a living body. More specifically, the invention "relates to devices and methods to occlude cardiovascular septal defects" (column 1, lines 7-8). As further explained at column 2, line 59, through column 3, line 2, the inventive devices

are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. . . . Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted vascular communication such as a patent ductus arteriosus.

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

The paragraph spanning columns 1 and 2 describes the basic features of the inventive device as follows:

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

Two embodiments of the inventive occlusion are described at column 2, lines 3-12, as follows:

In one embodiment [Figures 8 and 9], the occlusion-forming wire segments may comprise essentially flat helices [62a, 62b], urged toward one another. In another embodiment [Figures 1-5], the wire may further include two foldable membranes [21a, 21b], one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Appeal No. 2004-1453  
 Reexamination Control No. 90/006,043

The Applied Prior Art

The references cited by the examiner against the appealed claims in the examiner's answer are:<sup>1</sup>

Dotter	4,503,569	Mar. 12, 1985
Wiktor	4,649,922	Mar. 17, 1987
Palmaz	4,776,337	Oct. 11, 1988
Munster et al (Munster) <sup>2</sup> (Germany)	DD-233,303	Feb. 26, 1986

The Rejections

Claims 1-5, 9, 11, 14, 15, 19, 21, 34-39, 41-44, 46-64, 66-68, 70-75, 77, 78 and 80 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, obvious under 35 U.S.C. § 103(a) over Munster.

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<sup>1</sup>The Dotter, Wiktor and Palmaz references were cited against the claims for the first time in the examiner's answer. The examiner justifies this circumstance by stating that "the newly cited references are added merely as evidence of the prior well known statement by the examiner in accordance with M.P.E.P. 1208.01" (answer, page 3). Appellant has not petitioned the Director pursuant to 37 CFR § 1.181 with respect to the citation of these references, or the rejections based thereon. See page 5 of the reply brief.

<sup>2</sup>Our understanding of this German language document is derived in part from a translation thereof provided by appellant. A copy of that translation is attached to the decision.

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

Claims 6, 16, 17, 20, 40 and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster in view of Dotter.

Claims 10 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster in view of Wiktor.

Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster in view of Palmaz.

Claims 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster.

Attention is directed to appellant's main and reply briefs (Paper Nos. 31 and 33) and to the examiner's answer (Paper No. 32) for the respective positions of appellant and the examiner regarding the merits of these rejections.

The Munster Reference

Munster, the starting point for each of the examiner's rejections, is directed to a device for occluding an aperture within a body surface.<sup>1</sup> Figure 1 shows a first embodiment of an

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<sup>1</sup>Although Munster's drawing figures show the device occluding a duct between the body's main artery (aorta) and the pulmonary artery, it is clear that Munster contemplates the device being used to occlude an aperture in a body surface. See page 5 of the translation, lines 2-4 ("The present invention relates to an occluding object for occlusion of the ductus arteriosus persistens as well as other arteriopulmonary and other congenital or acquired arteriovenous fistulae, or heart defects.").

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

occluding device where the device comprises a wire of shape memory material which forms, when not influenced by outer forces, a so-called double helix configuration comprising relatively wide end portions 2, 3 and a narrow waist or central bridge portion 5. Figure 2 shows a second embodiment where the occluding device comprises several wire elements which comprise a central bridge portion 5 and a number of anchor arms 8 at each end of the bridge portion, which arms spread laterally when the device is subject to no external influences. The occluding device may be provided with textile fibers or bristles (elements 9 of Figure 1). Also, the bridge portion of the device may be provided with either an inflatable balloon (not shown) or a compressible, swelling plastic foam member (element 10 of Figure 2) to assist in occluding the aperture. In each embodiment, the ends of the occluding device are adapted to be compressed so that the device can be fit into a small diameter catheter (element 4 of Figure 3) for delivery to the site of the aperture to be occluded. When the device is released from the end of the catheter at the site of the aperture, the ends automatically re-assume the shape they exhibited when not influenced by outer forces (i.e., the shapes shown in Figures 1 and 2).

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

The method of placing the occluding device is set forth on pages 8-9 of the translation. Pertinent to the issues of patentability raised in the present case are the steps designated (e) through (k), which are reproduced below, with emphasis added:

- e) positioning of the catheter in the duct is such a manner that the front side lies in the aorta-side opening of the duct;
- f) introduction of the guide spiral provided with the holding wire and the occluding object, or the likewise equipped plastic catheter, into the catheter situated in the body, in such a manner that the occluding object is situated inside the catheter lumen in a stretched form . . . .
- g) retraction of the catheter, the guide spiral being held fast, in such a manner that upon the retraction of the catheter the front, longer anchor arms of the occluding object emerge from the catheter mouth and come to rest against the wall of the aorta, or in the case of the use of the double helix, the (for now) still-stretched aorta-side end, is pushed out of the catheter up to the central bridge, spreads itself out into its original form, and likewise comes to rest against the aorta wall, in both cases, the occluding object is still held fast at the pulmonary-side end by means of the holding wire;
- h) precise positioning of the aorta-side anchor arms, or as the case may be, the aorta-side end of the double helix, and further retraction of the catheter, until the pulmonary-side anchor arm or, as the case may be, the pulmonary end of the double helix, emerges from the catheter and comes to rest against the tissue around the opening of the duct on the pulmonary side;
- i) post-adjustment of the occluding object with the aid of the guide spiral and the holding wire affixed therein;
- j) letting the plastic swell up or inflating the balloon with an X-ray contrast agent at the central

Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

bridge of the occluding object, which is still  
fastened to the holding wire;

- k) injection of a contrast agent through the catheter  
for checking the sufficiency of the tightness of the  
closing off of the duct . . . .

Appellant's Article Claims

Analysis of whether a claim is patentable over the prior art begins with a determination of the scope of the claim. In the present case, we consider appellant's article claims to be directed to an occluding device *per se*, as opposed to an occlusion device positioned in an aperture in a body. Based on appellant's overall disclosure (see, for example, column 1, lines 61-65), we consider the claimed "preprogrammed configuration" of the occluding device to be the predetermined configuration the device is meant to assume when the device is at the normal body temperature of the site of its intended use. Based on appellant's overall disclosure (see, for example, column 1, lines 5-7; column 6, lines 18-22), we consider the terminology "occlusion-forming wire segments . . . urged toward one another" of representative claim 1, as well as the similar "urged toward one another" terminology of remaining independent article claims 9, 47, 57, 61-64 and 67, to mean that the wire segments of the claimed device are formed such that, in use, they press toward one another to engage the adjacent septal

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surfaces of the aperture to be occluded with sufficient force to occlude (i.e., block blood flow through) the aperture.

Representative article claim 1 is directed to a device adapted to occlude (i.e., block blood flow through) an aperture within a body surface. The device comprises a wire having two configurations, one such configuration being an elongated configuration for passage through a catheter and through the aperture, and the other configuration being a "preprogrammed configuration" which includes "occlusion-forming wire segments one on each side of said aperture urged toward one another." The claimed device further includes means for causing the wire to change from the elongated configuration to the preprogrammed configuration inside the body, said means being a temperature responsive material construction of the wire, by which the wire is activated at body temperature, to assume the preprogrammed configuration.

In rejecting the appellant's article claims as being anticipated by or, in the alternative, obvious in view of Munster, the examiner has advanced several alternative theories as to how the occluding device of Munster meets or renders obvious the limitations of the independent claims calling for the device to have a "preprogrammed configuration" wherein the occlusion-forming

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wire segments are "urged toward one another." First, the examiner contends (answer, page 5) that the wire segments of Munster are urged toward one another since they move radially outward and longitudinally toward each other as they emerge from the catheter. While we appreciate that the ends of Munster's device expand radially outwardly and most likely move toward each other, at least to some degree, as the device is being deployed, we must agree with appellant's argument on page 14 of the main brief that this circumstance does not meet the "urged toward each other" limitation of appellant's article claims in that these claims call for the occlusion-forming wire segments to be urged toward one another in the preprogrammed configuration, not during the transition of the occluding device from its elongated configuration into its preprogrammed configuration. Hence, the examiner's first theory of anticipation is not well taken.

Second, the examiner contends that Munster's disclosure that the ends of the occluding device come to rest against the tissue on the aorta and pulmonary arteries is sufficient to meet the "urged toward each other" language of the independent article claims because "it would certainly be very difficult, if not impossible, to size the Munster occluding member so that the wire segments, when they come to rest against the tissue, would not press against

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the tissue even in infinitesimal amount (i.e., with exactly zero force). Note that the amount "urged" is not claimed" (answer, page 10). Our difficulty with this argument is that, based on our interpretation *supra* of the "urged toward each other" language in appellant's claims, we do not consider that merely coming to rest against the walls of aorta and pulmonary arteries as called for in Munster, or lightly touching such tissue, would necessarily result in a device capable of occluding (i.e., blocking of blood flow through) the duct, as we consider the claims to require. This is especially so in that, from our perspective, steps (g) through (k) of Munster indicate that the mere coming to rest of the ends of the device against the aorta and pulmonary arteries is not, in and of itself, sufficient to close off the duct therebetween. More particularly, Munster's step (i) of post adjustment of the occluding object with the aid of the guide spiral and the holding wire indicates to us that the occluding device is at this stage of deployment still rather loosely positioned relative to the duct, and Munster's step (j) of swelling the plastic member or inflating the balloon and step (k) of only thereafter checking the sufficiency of the tightness of the closing off of the duct indicate to us that the plastic member or balloon plays an

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important role in attaining sufficient tightness to close off or occlude the duct.

Third, the examiner takes the alternative position in the paragraph spanning pages 5-6 of the answer that

assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed position.

In the present case, the examiner's assertion that Munster's teachings are sufficient to establish under the principles of inherency the particular "preprogrammed configuration" wherein the occlusion-forming wire segments are "urged toward one another" as called for in claim 1 and appellant's other independent article claims is totally without support in the Munster reference and entirely speculative on the examiner's part. In this regard, it is well settled that inherency may not be established by probabilities or possibilities, but must instead be "the natural result flowing from the operation as taught." See *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Here, there is no basis to believe that the ends of Munster's Figure 1 embodiment necessarily would be urged toward one another in the event that embodiment was

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placed in a duct of judiciously selected length slightly greater than that envisioned by the reference because, for all Munster teaches, the coils in the transition area between the ends of the device and the waist portion might simply contract to allow the length of the waist portion to "grow" to accommodate the increased length of the duct. As for Munster's Figure 2 embodiment, placing that device in a duct of slightly greater length than that envisioned by the reference also would not necessarily result in the kind of "urging toward each other" we consider the claims to require<sup>4</sup> since in this circumstance the occlusion function (i.e., blockage of blood flow) might be derived only from the swellable plastic member 10 or inflatable balloon this embodiment would appear to require. In light of the above, neither the Munster reference nor the examiner's reasoning provides an adequate factual basis to establish that the natural result flowing from following

---

<sup>4</sup>As stated *supra*, we consider the terminology "occlusion-forming wire segments . . . urged toward one another" of representative claim 1, as well as the similar "urged toward one another" terminology of remaining independent article claims 9, 47, 57, 61-64 and 67, to mean that the wire segments of the claimed device are formed such that, in use, they press toward one another to engage the adjacent septal surfaces of the aperture to be occluded with sufficient force to occlude (i.e., block blood flow through) the aperture.

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the teachings of Munster would be an occluding device like that claimed by appellant in the appealed article claims.

Looking finally at the examiner's 35 U.S.C. § 103(a) rejection of claim 1 et al. as being unpatentable over Munster, the examiner posits on page 10 of the answer that "[t]here is no teaching in Munster that the wire segments, as they are intended to operate, do not press against the tissue," and that "[i]t certainly would have been obvious to size them so that they press against tissue when implanted in the body in order to insure that they come to rest against tissue as intended."

Rejections based on 35 U.S.C. § 103 must rest on a factual basis. In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Moreover, while common knowledge and common sense may be applied to the analysis of evidence relied upon in making a rejection under 35 U.S.C. § 103, they are not a substitute for evidence. *In re Lee*, 277 F.3d 1338, 1345, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002). Here, the examiner's attempt to bridge the

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evidentiary gap between Munster and the claimed invention under the cover of what "certainly would have been obvious" to one of ordinary skill in the art and/or the circumstance that there is no teaching in Munster of the wire segments not pressing against the tissue is unavailing in that it rests on undue speculation and unfounded assumptions as to how the artisan might have gone about applying the teachings of Munster to repair congenital or acquired heart defects or the like. In this regard, the mere fact that the prior art could be modified to arrive at the claimed subject matter does not suffice. See *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

In light of the foregoing, we shall not sustain the examiner's rejection of claims 1-5, 9, 15, 19, 21, 34-39, 41-44, 46-64, 66-68, 70-75, 77, 78 and 80 as being anticipated by or, in the alternative, obvious over Munster.

Claims 6, 16, 17, 20, 40 and 45 stand rejected as being unpatentable further in view of Dotter, claims 10 and 20 stand rejected as being unpatentable further in view of Wiktor, and claims 7 and 8 stand rejected further in view of Palmaz. We have carefully reviewed the teachings of Dotter, Wiktor and Palmaz but find nothing therein which makes up for the deficiencies of Munster

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discussed above. Accordingly, we also shall not sustain the standing § 103 rejections of these dependent claims.

Appellant's Method Claims

Independent method claim 11 is directed to a method of occluding an aperture with a body surface. Claim 11 positively calls for, among other things, the steps of deploying a wire of temperature responsive material in an elongated configuration through a catheter, permitting the wire to assume a preprogrammed configuration whereupon an occlusion-forming wire segment on the distal side of the aperture is urged toward the aperture, and withdrawing the catheter thereby deploying an additional length of wire on the proximal side of the aperture whereupon the additional length of wire is permitted to assume a preprogrammed configuration including an opposing occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture.

The views we expressed above concerning the rejection of appellant's article claims apply with equal force to the examiner's rejection of method claims 11, and claims 12-14 that depend therefrom. Simply stated, Munster does not anticipate or render obvious appellant's method claims any more than it did appellant's article claims. Accordingly, we also shall not sustain the

REVERSED

IRWIN CHARLES COHEN  
Administrative Patent Judge

*Lawrence J. Staab*  
LAWRENCE J. STAAB  
Administrative Patent Judge

JEFFREY V. NASE  
Administrative Patent Judge

BOARD OF PATENT  
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Appeal No. 2004-1453  
Reexamination Control No. 90/006,043

BLANK ROME LLP  
600 NEW HAMPSHIRE AVENUE, NW  
WASHINGTON, DC 20037

**EXHIBIT P**



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Press Release

Source: NMT Medical, Inc.

## NMT Medical Announces Favorable Decision by U.S. Patent Office Board of Appeals

Tuesday September 7, 3:16 pm ET

BOSTON, Sept. 7 /PRNewswire-FirstCall/ -- NMT Medical, Inc. (Nasdaq: [NMTI](#) - [News](#)) today announced a favorable decision by the U.S. Patent and Trademark Office Board of Appeals relating to the Company's patent infringement actions against AGA Medical Corp.

In December 1998, NMT filed a patent infringement suit against AGA Medical claiming that certain of AGA's products infringe U.S. Patent No. 5,108,420 (the '420 Patent), which is exclusively licensed by NMT. During the litigation, AGA identified certain third party patents that it argued would invalidate the claims of the '420 Patent. In September 2003, the Court dismissed NMT's suit against AGA without prejudice to NMT's ability to refile the suit after the conclusion of the reexamination proceedings.

Although a Patent Office examiner initially rejected the claims of the '420 Patent, the Patent Office Board of Appeals reversed the examiner's rejection of the claims on August 19, 2004 and returned the reexamination for action consistent with its decision.

John E. Ahern, NMT's President and CEO, said, "The Board of Appeals' decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively."

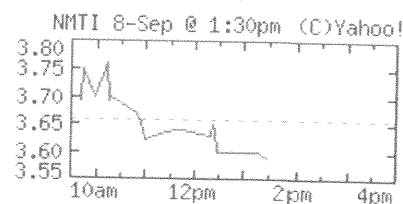
About NMT Medical, Inc.

NMT Medical designs, develops and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of stroke and other brain attacks through minimally invasive, catheter-based procedures. NMT Medical is investigating the potential connection between a common cardiac defect called a patent foramen ovale (PFO) and brain attacks such as stroke, transient ischemic attacks (TIA's) and migraine headaches. A PFO can allow venous blood, unfiltered by the lungs, to enter the arterial circulation of the brain possibly triggering a cerebral event or brain attack. NMT is the leader in designing and developing implants to seal the PFO defect in a minimally invasive, catheter-based procedure performed by the interventional cardiologist.

Stroke is the third leading cause of death in the United States and leading cause of disability in adults. Each year 750,000 Americans suffer a new or recurrent stroke and 500,000 Americans experience a TIA. The prevalence of migraines in the United States is about 10%. Of the 28 million migraine sufferers in America, three out of four are women. Migraines have increased 50% in the last 20 years.

The Company also serves the pediatric interventional cardiologist with a broad range of cardiac

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septal repair implants delivered with nonsurgical catheter techniques. For more information about NMT Medical, please visit <http://www.nmtmedical.com>.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements -- including statements regarding the timing and ultimate outcome of any administrative and litigation proceedings to enforce the Company's intellectual property rights and the Company's financial, sales and profitability expectations, expansion of the Company's cardiovascular business and market opportunities, including migraines and any other new applications for our technology or products, the timing, cost and outcome of CLOSURE I, expected patient enrollment levels and the timing thereof, regulatory approvals for the Company's products, new products and product developments -- involve known and unknown risks, uncertainties or other factors which may cause actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that may cause such a difference include, but are not limited to, the risk factors discussed under the heading "Certain Factors That May Affect Future Results" included in Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10-K for the year ended December 31, 2003, as amended, and subsequent filings with the U.S. Securities and Exchange Commission.

Contact:  
John E. Ahern  
President & Chief Executive Officer  
NMT Medical, Inc.  
(617) 737-0930  
[jea@nmtmedical.com](mailto:jea@nmtmedical.com)

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**EXHIBIT Q**



**John E. Ahern**  
President and  
Chief Executive Officer

September 14, 2004

NMT Medical, Inc.

**By UPS Overnight**

27 Wormwood Street

Boston, MA 02210-1625

VOICE: 617.737.0930 EXT. 101

FAX: 617.737.0626

EMAIL: [jea@nmtmedical.com](mailto:jea@nmtmedical.com)

[www.nmtmedical.com](http://www.nmtmedical.com)

John W. Borg  
Receiver/Interim CEO  
AGA Medical Corporation  
682 Mendelssohn Avenue  
Golden Valley MN 55427

Re: Recent Developments at the US PTO Board of Appeals

Dear Mr. Borg:

As you are no doubt aware, in December 1998, NMT Medical filed a patent infringement suit against AGA Medical claiming that certain of AGA's products infringe U.S. Patent No. 5,108,420 (the '420 Patent), which is exclusively licensed by NMT. During the litigation, AGA identified certain third party patents that it argued would invalidate the claims of the '420 Patent.

As you should also be aware, the '420 patent has been the subject of a reexamination procedure in the U.S. Patent and Trademark Office ("PTO") to determine the validity of the patent in light of the documents identified by AGA. In September 2003, the Court dismissed NMT's suit against AGA without prejudice to NMT's ability to refile the suit after the conclusion of the reexamination proceedings by the U.S. PTO. Although a Patent Office examiner initially rejected the claims of the '420 Patent, the Patent Office Board of Appeals reversed the examiner's rejection of the claims on August 19, 2004 and returned the reexamination for action consistent with its decision.

In light of this material development and as part of NMT's ongoing efforts to defend its intellectual property, we would like to discuss an appropriate resolution to this matter either in person or by telephone at your earliest convenience. I can be reached at (617) 737-0930, extension 101 or by email at [jea@nmtmedical.com](mailto:jea@nmtmedical.com).

I look forward to hearing from you.

Sincerely,

  
\_\_\_\_\_  
John E. Ahern

**EXHIBIT R**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

---

AGA Medical Corporation.,

Plaintiff,

v.

Civil Action # \_\_\_\_\_

Nitinol Medical Technologies, Inc.,  
d/b/a/ NMT Medical, Inc, and  
Lloyd A. Marks

Defendants.

---

**COMPLAINT FOR DECLARATORY RELIEF**

---

For its complaint against Nitinol Medical Technologies, Inc. ("NMT") and Lloyd A. Marks (hereinafter referred to collectively as "Defendants"), Plaintiff AGA Medical Corp. states and alleges as follows:

**PARTIES**

1. Plaintiff, AGA Medical Corp. ("AGA") is a corporation duly organized and existing under the laws of the State of Minnesota with its principal place of business in Golden Valley, Minnesota.

2. NMT is a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business in Boston, Massachusetts.

3. Lloyd A. Marks is a resident of the state of New Jersey.

**JURISDICTION**

4. This is a claim for, among other things, a declaratory judgment of patent invalidity and non-infringement.

5. This Court has jurisdiction over AGA's federal claims by virtue of the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. This Court has personal jurisdiction over the Defendants. NMT knowingly and intentionally exploits the Minnesota market through advertising and sales of its products. Mr. Marks knowingly and intentionally exploits the Minnesota market through the royalties he receives under his exclusive licensing agreement with NMT.

#### VENUE

7. A substantial part of the events or omissions giving rise to AGA's cause of action occurred in this judicial district.

8. By reasons of the foregoing, venue of this action is proper in this Court pursuant to the provisions of 28 U.S.C. § 1391(b).

#### **COUNT I : INVALIDITY AND NON-INFRINGEMENT OF PATENT**

9. AGA restates Paragraphs 1-7 of this Complaint.

10. Lloyd A. Marks claims to be the owner of U.S. Patent No. 5,108,420 issued on April 28, 1992, attached hereto as Exhibit A (the "'420 Patent"). NMT claims that it is the exclusive licensee of the '420 Patent.

11. As a result of the acts set forth below, an actual justiciable controversy exists between Defendants and AGA with respect to the validity of the '420 Patent and Defendants' claims that AGA's products infringe the '420 Patent.

12. On December 10, 1998, Defendants commenced litigation in the U.S. District Court for the District of Massachusetts against AGA for infringement of the '420 Patent (hereinafter referred to as "the Massachusetts Litigation"). The Massachusetts Litigation was

captioned Nitinol Medical Tech v. AGA Medical Corp., 98-cv-12506-NG. A copy of the Complaint is attached hereto as Exhibit B.

13. On April 25, 2001, the District Court stayed the Massachusetts Litigation pending a reexamination of the '420 patent by the United States Patent and Trademark Office. A copy of the Order staying the Massachusetts Litigation is attached hereto as Exhibit C. On December 1, 2003, the District Court of Massachusetts dismissed the Massachusetts Litigation without prejudice. A copy of the Order dismissing the Massachusetts Litigation is attached as Exhibit D.

14. During the reexamination of the '420 Patent, the Patent Office Examiner rejected the claims. However, on August 19, 2004, the Patent and Trademark Office Board of Appeals purportedly reversed the examiner's rejection.

15. On September 7, 2004, Defendants issued a press release in which John E. Ahern, the President and CEO of NMT declared:

“[t]he Board of Appeals decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively.”

(emphasis added). A copy of the September 7<sup>th</sup> press release is attached as Exhibit E.

16. AGA's position has consistently been that it has not infringed the '420 Patent and that the '420 Patent is invalid and unenforceable.

17. By virtue of the exchanges outlined above, there is a substantial and continuing justiciable controversy between AGA and Defendants as to Defendants' rights in the '420 Patent, the validity and enforceability of the '420 Patent, and as to AGA's continuing right to make, use and sell its products.

18. AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA by the making, using or selling of any product.

19. In the alternative, AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable, and void since they have not and may not be duly or legally issued for many reasons including, without limitation, that each are invalid, unenforceable, and void given the statutory requirements of 35 U.S.C. §§ 102, 103 or 112 for one or more of the following reasons:

- a. The patentee did not invent the subject matter patented, nor did he make any invention or discovery, either novel, original, or otherwise, within the meaning of United States Code, Title 35;
- b. The alleged invention was made by another in this country before the patentee's alleged invention, and such other person had not abandoned, suppressed, or concealed it;
- c. The patent does not particularly point out and distinctly claim the part, improvement, method, steps, or combination that the patentee claims as his invention, as required by Title 35, United States Code;
- d. The specification does not contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it

pertains, or with which it most nearly connected, to make, construct, compound and/or use the same, and the description does not adequately explain the principle or the best mode in which the patentee contemplated applying the principle so as to distinguish it from other inventions, as required by Title 35, United States Code;

e. The claims, and each of them, of the patent are excessively vague and indefinite and do not distinctly point out and define the invention;

f. The claims, and each of them, are not directed to patentable combinations, but are directed to mere aggregations of parts or steps, means, or elements which were matters of common knowledge in the art to which said patent relates before the alleged invention and more than one year prior to the date of the application for the patent;

g. In light of the prior art at the time the alleged invention was made, the subject matter as claimed in the patent would have been obvious to one skilled in the art to which the alleged invention relates and does not constitute patentable invention;

h. The alleged invention or discovery was disclosed in a U.S. patent to another, the application for which was filed before the alleged invention by the patentee of the Patents-in-Suit;

i. More than one year prior to the filing of the original application which matured into the Patents-in-Suit, the alleged invention was patented or described in printed publications in this or in foreign countries, or was in public use, or on sale in this country;

j. Before the alleged invention or discovery of the patentee, the alleged invention was known or used by others than the alleged inventor and was on sale in this country and was patented or described in a printed publication in this or in foreign countries.

20. AGA further avers that any claims of the '420 Patent, including any claims which may have survived reexamination, which may be held to be valid are so restricted in scope that AGA has not infringed said claims.

21. As a result of the proceedings in the U.S. Patent and Trademark Office during the prosecution of the applications and reexamination proceedings for the '420 Patent and the admissions and representations made in the proceedings by or on behalf of the applicant, Defendants is estopped under the doctrine of prosecution history estoppel and may not now seek or maintain a construction for the claims of the '420 Patent, were the same otherwise possible, to cover or embrace any products made, used, or sold by AGA.

22. AGA has not done any act or thing and is not proposing to do any act or thing in violation of any rights validly belonging to Defendants under any patent owned by Defendants. The '420 Patent is invalid and unenforceable, and not infringed by AGA, and AGA is not liable for infringement of said patents.

PRAYER

WHEREFORE, AGA prays that:

1. Entry of judgment providing:

a. A declaration that Defendants is without right or authority to threaten or maintain suit against AGA for alleged infringement of the '420 Patent, including any claims which may have survived reexamination.

b. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable and void in law.

c. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

d. AGA be awarded its costs and attorneys fees related to this suit.

e. Preliminary and permanent injunctive relief enjoining Defendants, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with it who receive actual notice of the injunction from initiating infringement litigation or threatening AGA or any of its customers, dealers, agents, servants, or employees, or any perspective or present sellers, dealers, or users of AGA's products, with infringement litigation, or charging any of them verbally or in writing with infringement of the '420 Patent because of the manufacture, use, sale, or offering for sale of the AGA's products.

2. All other relief that the Court may deem appropriate.

Respectfully submitted,

Dated: September 9, 2004

NIKOLAI & MERSEREAU, P.A.

s/ James T. Nikolai

---

James T. Nikolai (#0144101)

Peter G. Nikolai (#0322052)

900 Second Avenue South

820 International Centre

Minneapolis, MN 55402

Phone: (612)339-7461

Fax: (612)349-6556

**Attorneys for Plaintiff  
AGA MEDICAL CORP.**

PATENT

**U.S. District Court  
District of Minnesota (DMN)  
CIVIL DOCKET FOR CASE #: 0:04-cv-04486-JMR-FLN**

AGA Medical Corporation v. Nitinol Medical Technologies Inc et al  
Assigned to: Chief Judge James M Rosenbaum  
Referred to: Magistrate Judge Franklin L Noel  
Cause: 35:145 Patent Infringement

Date Filed: 10/13/2004  
Jury Demand: None  
Nature of Suit: 830 Patent  
Jurisdiction: Federal Question

**Plaintiff**

**AGA Medical Corporation**

represented by **James T Nikolai**  
Nikolai & Mersereau  
820 International Ctr  
900 2nd Ave S  
Mpls, MN 55402  
(612) 339-7461  
Fax: 6123496556  
Email: jim@nm-iplaw.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Peter G Nikolai**  
Nikolai & Mersereau  
820 International Ctr  
900 2nd Ave S  
Mpls, MN 55402  
(612) 339-7461  
Email: peter@nm-iplaw.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Nitinol Medical Technologies Inc**  
*doing business as*  
NMT Medical, Inc.

represented by **Erin C Skold**  
Leonard Street and Deinard  
150 5th St S Ste 2300  
Mpls, MN 55402  
(612) 335-1500  
Fax: 6123351657  
Email: erin.skold@leonard.com  
*LEAD ATTORNEY*

**Defendant**

**Lloyd A Marks**

Date Filed	#	Docket Text
10/13/2004	<u>1</u>	COMPLAINT against Lloyd A Marks, Nitinol Medical Technologies Inc , filed by AGA Medical Corporation. ASSIGNED TO CHIEF JUDGE JAMES M. ROSENBAUM PER PATENT LIST AND REFERRED TO MAGISTRATE JUDGE FRANKLIN L. NOEL, rcpt. no. 432926, (Filing fee \$ 150.) (Attachments: # <u>1</u> Exhibits# <u>2</u> Civil Cover Sheet)(DFL) (Entered: 10/14/2004)
10/13/2004		Summons Issued as to Lloyd A Marks, Nitinol Medical Technologies Inc. (DFL) (Entered: 10/14/2004)
01/27/2005	<u>2</u>	*** FILING ERROR - DOCUMENT TO BE RE-FILED*** Return of Service Executed for Summons and Complaint served on Jessina Hue on January 20, 2005, filed by AGA Medical Corporation. (Nikolai, Peter) Modified on 1/28/2005 (GJS). (Entered: 01/27/2005)
01/27/2005	<u>3</u>	SUMMONS Returned Executed by AGA Medical Corporation. Lloyd A Marks served on 1/20/2005, answer due 2/9/2005. (Nikolai, Peter) (Entered: 01/27/2005)
01/27/2005	<u>4</u>	RULE 7.1 DISCLOSURE STATEMENT of AGA Medical Corp. No parent corporation. (Attachments: # <u>1</u> Certificate of Service)(Nikolai, Peter) Modified text on 1/28/2005 (gjs). (Entered: 01/27/2005)
01/28/2005	<u>5</u>	SUMMONS Returned Executed by AGA Medical Corporation. Nitinol Medical Technologies Inc served on 1/20/2005, answer due 2/9/2005. (Nikolai, Peter) (Entered: 01/28/2005)
02/07/2005	<u>6</u>	STIPULATION to Extend Time for Filing Answer to Complaint for Declaratory Relief by Nitinol Medical Technologies Inc. (Attachments: # <u>1</u> )(Skold, Erin) (Entered: 02/07/2005)
02/07/2005	<u>7</u>	CERTIFICATE OF SERVICE by Nitinol Medical Technologies Inc of Proposed Order to Extend Time for Filing Answer to Complaint (Skold, Erin) (Entered: 02/07/2005)

PACER Service Center			
Transaction Receipt			
02/08/2005 12:16:51			
PACER Login:	nm0073	Client Code:	AGA
Description:	Docket Report	Search Criteria:	0:04-cv-04486-JMR-FLN
Billable Pages:	1	Cost:	0.08

**EXHIBIT S**

AW OFFICES  
NIKOLAI &  
MERSEREAU, P.A.

October 14, 2004

VIA FAX; FIRST CLASS MAIL

Dominic E. Massa, Esq.  
HALE AND DOOR LLP  
60 State Street  
Boston, MA 02109

Re: NMT v. AGA  
Civil Action No. 98-12506 (NG)

Dear Dominic:

This is a follow-up to the voicemail message I left you the other day and in reply to your client's letter to John Borg, the receiver for AGA Medical Corporation, suggesting that the parties get together to discuss a resolution of issues related to the Marks patent.

My client is interested in hearing what your client has to say in this regard. The ownership of AGA has asked Mr. Borg, Michael O'Rourke, who is working with the receiver, and me to make ourselves available for such a meeting. We would be happy to host such a meeting here in Minneapolis. Please let me know what dates will work for you and your client.

As I am sure you can appreciate, my client was very concerned about the press release that your client issued regarding the reexamination proceedings and containing references to alleged infringement by AGA. It took us some time to obtain copies of the Board of Appeals' decision. We have now received that decision, analyzed it and have discussed it with AGA's Board of Directors and management. Under separate cover I have sent you a letter outlining some issues that we believe should be brought to the attention of the Examiner. We have also filed a declaratory judgment action in the U.S. District Court for the District of Minnesota related to the Marks patent. Before serving the Complaint, however, we agree that it is worth discussing with you the opportunities for resolution suggested by Mr. Ahern's letter. If such discussions are to go anywhere, both sides must be candid with each other. That is why I wanted

Dominic Massa, Esq.  
October 14, 2004  
Page 2

you to hear from us, rather than independently learn, of the declaratory action judgment action we have filed.

After you have had an opportunity to discuss the foregoing with your client, please contact me so we can put the parties together to discuss possible ways to resolve the differences.

Sincerely,

NIKOLAI & MERSEREAU, P.A.

  
James T. Nikolai

JTN:br

cc: John Borg  
Michael O'Rourke  
Michael Afremov  
Franck Gougeon

## The Submission Report

Date/Time  
Local ID  
Local Name  
Company Logo

10-14-04; 2:38PM  
612 349 6556  
NIKOLAI MERSEREAU

This document was confirmed.  
(reduced sample and details below)  
Document Size Letter-S

NIKOLAI & MERSEREAU, P.A.  
900 SECOND AVENUE SOUTH, SUITE 820  
MINNEAPOLIS, MN, U.S.A. 55402-3325  
Telephone: (612) 339-7461 Facsimile: (612) 349-6556

## FACSIMILE TRANSMISSION

## TO:

Name: Dominic Massa, Esq.  
Firm : HALE AND DOOR LLP  
City : State:

Fax No.: 617-526-5000

Country: USA

## FROM:

Name: James Nikolai  
NIKOLAI & MERSEREAU, P.A., 900 Second Ave. S., #820, Minneapolis, MN 55402, U.S.A.

Fax No.: (612) 349-6556

DATE: 10/14/04

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## Notes :

EC: Error Correct  
BC: Broadcast Send  
CP: Completed  
HS: Host Scan  
HF: Host Fax

RE: Resend  
MP: Multi-Poll  
RM: Receive to Memory  
HP: Host Print  
HR: Host Receive

PD: Polled by Remote  
PG: Polling a Remote  
DR: Document Removed  
FO: Forced Output  
FM: Forward Mailbox Doc.

MB: Receive to Mailbox  
PI: Power Interruption  
TM: Terminated by user  
WT: Waiting Transfer  
WS: Waiting Send

**EXHIBIT T**

**RETURN OF SERVICE**

UNITED STATES DISTRICT COURT  
District of Minnesota

Case Number: 04-4486JMR/FLN

Plaintiff:

**AGA Medical Corporation**

vs.

Defendant:

**Nitinol Medical Technologies, Inc., et al**

Received by MASS CONSTABLE SERVICE to be served on **NITINOL MEDICAL TECHNOLOGIES, 27 Wormwood St., Boston, MA 02210.**

I, David Brown, do hereby affirm that on the **20th day of January, 2005** at **1:40 pm**, I:

Served a true and attested copy of the **US Summons; Complaint; Civil Cover Sheet; Exhibit to Nitinol Medical Technologies** in the following manner, by delivering in hand to **Jessina Hue, authorized agent.** . Said service was made at **27 Wormwood St., Boston, MA 02210 .**

**Description** of Person Served: Age: 30, Sex: F, Race/Skin Color: Black, Height: 5'6", Weight: 130, Hair: Black, Glasses: N

I certify that I am over the age of 18, have no interest in the above action.



**David Brown**  
Process Server

**MASS CONSTABLE SERVICE**  
**1004 Pheasant Lane**  
**Middleboro, MA 02346**  
**(800) 249-3155**

Our Job Serial Number: 2005000185  
Ref: 543

**EXHIBIT U**

## UNITED STATES DISTRICT COURT

District of

AGA MEDICAL CORPORATION

## SUMMONS IN A CIVIL CASE

V.

Nitinol Medical Technologies, Inc.,  
d/b/a/ NMT Medical, Inc, and  
Lloyd A. Marks

CASE NUMBER: 04-4486JMR/FLN

TO: (Name and address of Defendant)

NITINOL MEDICAL TECHNOLOGIES  
27 WORMWOOD ST  
BOSTON, MA 02210-1619 UNITED STATES

Mr. Lloyd A. Marks  
1021 MINISINK WAY  
WESTFIELD, NJ 07090-3722

**YOU ARE HEREBY SUMMONED** and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

James T. Nikolai (#0144101)  
NIKOLAI & MERSEREAU, P.A.  
900 Second Avenue South  
820 International Center  
Minneapolis, MN 55402

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

RICHARD D. SLETTEN

CLERK


OCT 13 2004

DATE

(By) DEPUTY CLERK

ORIGINAL

AO 440 (Rev. 10/93) Summons in a Civil Action - SDNY WEB 4/99

RETURN OF SERVICE		
Service of the Summons and Complaint was made by me <sup>1</sup>	DATE <u>1/20/05</u>	
NAME OF SERVER <u>ALFONSE R. CARLUCCI</u>	TITLE <u>Process Server</u>	
Check one box below to indicate appropriate method of service		
<input type="checkbox"/> Served personally upon the defendant. Place where served: _____		
<input checked="" type="checkbox"/> Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left: <u>JANICE SIEGEL, WIFE</u>		
<input type="checkbox"/> Returned unexecuted: _____		
<input type="checkbox"/> Other (specify): _____		
STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES	TOTAL
DECLARATION OF SERVER		
<p>I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%;"> <p>Executed on <u>1.20.05</u></p> <p style="text-align: center;">Date</p> </div> <div style="width: 45%; text-align: center;">   <p>Signature of Server</p> </div> </div> <div style="margin-top: 20px; text-align: center;"> <p><u>1 Woodside Rd, Springfield, NJ 07081</u></p> <p>Address of Server</p> </div>		

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.  
2298

**EXHIBIT V**

FILED  
IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

2005-1 P 3:15

U.S. DISTRICT COURT  
DISTRICT OF MASS.

Civil Action No. \_\_\_\_\_

JURY TRIAL DEMANDED

RECEIPT # 11662  
AMOUNT USD  
SUMMONS ISSUED Y  
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WAIVER FORM +  
MCF ISSUED +  
BY DPTY. CLK. FOW  
12/10/04

NMT MEDICAL, INC.,

Plaintiff,

v.

AGA MEDICAL CORPORATION,

Defendant.

04-12565 NG

**COMPLAINT FOR PATENT INFRINGEMENT**

**NATURE OF ACTION**

This is an action under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,108,420.

**THE PARTIES**

1. Plaintiff NMT Medical, Inc. ("NMT") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Boston, Massachusetts.

2. Defendant AGA Medical Corporation ("AGA"), is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

**JURISDICTION AND VENUE**

3. This is an action for patent infringement arising under Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a).

4. Venue is proper in this jurisdiction pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

### **ACTS GIVING RISE TO THE COMPLAINT**

5. Plaintiff NMT is the exclusive worldwide licensee of the right to make, use, and sell products embodying and/or manufactured according to the methods of United States Patent No. 5,108,420 (the “420 patent”), entitled “Aperture Occlusion Device.” A complete and true copy of the ‘420 patent is attached as Exhibit A.

6. On December 10, 1998, NMT commenced litigation against AGA in this Court, alleging infringement of the ‘420 Patent. That litigation was captioned Nitinol Medical Technologies, Inc. v. AGA Medical Corp., 98-cv-12506-NG.

7. During the course of the parties’ prior litigation, it became clear that two pieces of purported prior art were not before the Patent and Trademark Office (“PTO”) when the ‘420 patent originally was prosecuted.

8. On April 25, 2001, the Court granted NMT’s motion to stay the proceedings in the parties’ original litigation pending reexamination of the ‘420 patent by the PTO.

9. Thereafter, on June 25, 2001, the inventor of the ‘420 patent voluntarily submitted the ‘420 patent to the PRO for reexamination in light of the purported prior art.

10. The Court held periodic status conferences during the following sixteen months. After each conference, the Court continued its order staying the proceedings. At a status conference on October 31, 2002, the Court indicated that it would consider dismissing the parties’ original litigation without prejudice if the PTO did not issue a decision on the reexamination proceeding by the end of 2002.

11. On February 5, 2003, the PTO examiner conducting the reexamination rejected all of the claims of the ‘420 patent. NMT timely sought review of the PTO examiner’s determination before the Board of Patent Appeals and Interferences.

12. On September 30, 2003, by letter to the Court, AGA requested that the ongoing stay of the parties' original litigation be converted into a dismissal without prejudice.

13. On December 2, 2003, while the PTO appeal was pending, the Court dismissed the parties' original litigation, without prejudice to NMT's right to refile the case in this Court depending upon the outcome of the PTO reexamination proceedings.

14. On August 19, 2004, the Board of Patent Appeals and Interferences reversed the PTO examiner's initial determination and found that the two pieces of purported prior art did not invalidate the claims of the '420 patent. The PTO Board remanded the '420 patent to the PTO examiner for proceedings consistent with the Board's decision.

15. On October 13, 2004, AGA brought a complaint against NMT in the District of Minnesota for a declaratory judgment regarding the issues of infringement and validity with respect to the '420 patent. AGA's Minnesota Complaint raises the same claims and defenses with regard to the '420 patent that were before this Court in the parties' original litigation.

#### **COUNT I: INFRINGEMENT**

16. NMT restates Paragraphs 1 – 15 of this Complaint.

17. AGA manufactures, offers for sale, or sells medical devices which infringe one or more of the claims of the '420 patent.

18. On information and belief, AGA's acts of infringement are willful and deliberate.

#### **PRAYER FOR RELIEF**

WHEREFORE, NMT requests that judgment be entered in its favor and that it be granted the following relief:

1. A judgment that AGA has infringed the '420 patent, and that such infringement has been willful;

2. A permanent injunction restraining AGA, its officers, agents, servants, and employees, and those acting in concert with it, from infringing the '420 patent.
3. An award of damages sufficient to compensate NMT for the infringement complained of herein;
4. An award of enhanced damages in the amount of three times the damages found or assessed, attorneys' fees, disbursements, and costs of suit; and
5. Such other and further relief as the Court deems just and proper.

**JURY TRIAL DEMAND**

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY.

Dated: December 7, 2004.

**NMT MEDICAL, INC.**

By its attorneys,



---

Dominic E. Massa (BBO #564694)  
Wilmer Cutler Pickering Hale and Dorr LLP  
60 State Street  
Boston, Massachusetts 02109  
(617) 526-6000

PATENT

**United States District Court  
District of Massachusetts (Boston)  
CIVIL DOCKET FOR CASE #: 1:04-cv-12565-NG**

NMT Medical, Inc. v. Aga Medical Corporation  
Assigned to: Nancy Gertner  
Related Case: 1:98-cv-12506-NG  
Cause: 35:271 Patent Infringement

Date Filed: 12/07/2004  
Jury Demand: Plaintiff  
Nature of Suit: 830 Patent  
Jurisdiction: Federal Question

**Plaintiff**

**NMT Medical, Inc.**

represented by **Cynthia D. Vreeland**  
Wilmer Cutler Pickering Hale and Dorr  
LLP  
60 State Street  
Boston, MA 02109  
617-526-6000  
Fax: 617-526-5000  
Email:  
cynthia.vreeland@wilmerhale.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**David L. Cavanaugh**  
Wilmer Cutler Pickering Hale and Dorr  
LLP  
60 State Street  
Boston, MA 02109  
617-526-6000  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Dominic E. Massa**  
Wilmer Cutler Pickering Hale and Dorr  
LLP  
60 State Street  
Boston, MA 02109  
617-526-6000  
Fax: 617-526-5000  
Email:  
dominic.massa@wilmerhale.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Katie Marie Saxton**  
Wilmer Cutler Pickering Hale and Dorr  
LLP

60 State Street  
 Boston, MA 02109  
 617-526-6000  
 Fax: 617-526-5000  
 Email: kate.saxton@wilmerhale.com  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

V.

**Defendant**

**Aga Medical Corporation**

represented by **John L. Capone**  
 Cesari and McKenna, LLP  
 88 Black Falcon Avenue  
 Boston, MA 02210  
 617-951-2500  
 Fax: 617-951-3927  
 Email: jcapone@c-m.com  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

Date Filed	#	Docket Text
12/07/2004	<u>1</u>	COMPLAINT against Aga Medical Corporation Filing fee: \$ 150, receipt number 60602, filed by NMT Medical, Inc.. (Attachments: # <u>1</u> Civil Cover Sheet # <u>2</u> Exhibit A)(Filo, Jennifer) (Entered: 12/08/2004)
12/07/2004		Summons Issued as to Aga Medical Corporation. (Filo, Jennifer) (Entered: 12/08/2004)
12/07/2004		If the trial Judge issues an Order of Reference of any matter in this case to a Magistrate Judge, the matter will be transmitted to Magistrate Judge Cohen. (Filo, Jennifer) (Entered: 12/08/2004)
12/07/2004	<u>2</u>	REPORT on the filing of copyright case. (Filo, Jennifer) (Entered: 12/16/2004)
02/02/2005	<u>6</u>	NOTICE of Appearance by Katie Marie Saxton, David L. Cavanaugh, Cynthia D. Vreeland on behalf of NMT Medical, Inc. (Patch, Christine) (Entered: 02/08/2005)
02/03/2005	<u>3</u>	NOTICE of Appearance by John L. Capone on behalf of Aga Medical Corporation (Capone, John) (Entered: 02/03/2005)
02/04/2005	<u>4</u>	Assented to MOTION for Leave to Appear Pro Hac Vice by James T. Nikolai , Esq. by Aga Medical Corporation. (Attachments: # <u>1</u> Certificate of Good Standing of James T. Nikolai, Esq.)(Capone, John) (Entered: 02/04/2005)
02/07/2005	<u>5</u>	STIPULATION <i>Extending Time to Answer</i> by Aga Medical Corporation. (Capone, John) (Entered: 02/07/2005)

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<b>PACER Service Center</b>			
<b>Transaction Receipt</b>			
02/08/2005 14:30:19			
<b>PACER Login:</b>	nm0073	<b>Client Code:</b>	aga
<b>Description:</b>	Docket Report	<b>Search Criteria:</b>	1:04-cv-12565-NG
<b>Billable Pages:</b>	1	<b>Cost:</b>	0.08

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